#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### Amendment No. 4 to

#### FORM S-1

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

#### IN8BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

2836

(Primary Standard Industrial Classification Code Number)

82-5462585

(I.R.S. Employer Identification Number)

79 Madison Avenue
New York, New York 10016
(646) 600-6438
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

William Ho President and Chief Executive Officer IN8bio, Inc. 79 Madison Avenue
New York, New York 10016
(646) 600-6438
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Joshua A. Kaufman Jaime L. Chase Joshua Rottner Cooley LLP 55 Hudson Yards New York, New York 10001 (212) 479-6000

Patrick McCall Chief Financial Officer IN8bio, Inc. 79 Madison Avenue New York, New York 10016 (646) 600-6438

Nathan Ajiashvili Latham & Watkins LLP 1271 Avenue of the Americas New York, New York 10020 (212) 906-1200

#### Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities

Act of 1933, check the following box. 

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement number of the earlier effective registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act

registration statement number of the earlier effective registration statement for the same offering. 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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  $\ \square$ 

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 7(a)(2)(B) of the Securities Act.  $\Box$ 

#### CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount of Registration Fee <sup>(3)</sup>		
Common Stock, \$0.0001 par value per share	\$46,000,000	\$5,019		

- Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended.
- (2)Includes the aggregate offering price of additional shares that the underwriters have the option to purchase, if any.
- (3) The registrant previously paid the registration fee in connection with the initial filing of this Registration Statement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

#### **Shares**



#### Common Stock

This is the initial public offering of common stock of IN8bio, Inc. We are selling shares of our common stock in this offering. We anticipate that the initial public offering price will be between \$ and \$ per share. Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "INAB." We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities

laws and, as such, may elect to comply with certain reduced public company reporting requirements for future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks. See "Risk Factors" beginning on page 11 of this prospectus.

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us, before expenses	\$	\$

<sup>(1)</sup> We have agreed to reimburse the underwriters for certain expenses. See "Underwriting" on page <u>167</u> for additional information regarding underwriting compensation.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

We have granted the underwriters an option to purchase up to cover overallotments, if any.

additional shares of common stock to

The underwriters expect to deliver the shares of our common stock to purchasers on or about

, 2021.

### **B. Riley Securities**

Prospectus dated

, 2021

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"IN8BIO," "INEIGHTBIO," the IN8BIO logo, DeltEx and other trademarks, trade names or service marks of IN8bio, Inc. appearing in this prospectus are the property of IN8bio, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the <sup>®</sup> and <sup>™</sup> symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto. The images found on pages 93, 95, 102, 108 and 112 of this prospectus were created with biorender.com.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside the United States.

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Until , 2021 (25 days after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "IN8bio, Inc.," "the company," "we," "us," "our" and similar references in this prospectus refer to IN8bio, Inc.

#### 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 gammadelta 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 vivoexpanded 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 initial results from the second cohort in this Phase 1 trial by the end of 2021 and initial Phase 1 results from the third cohort 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 topline results for all cohorts 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 in the first half of 2022 and in 2023.

Chemotherapy, a mainstay of solid tumor treatment, can deplete and damage immune cells, limiting their ability to seek and kill tumors. Despite these limitations, chemotherapy continues to be used in standard-of-care regimens because of its ability to directly kill tumors. However, residual tumor cells, which are chemotherapy resistant, often remain and lead to disease recurrence. This is further compounded by the lymphodepleting properties of chemotherapy, which can severely reduce the number of immune cells, such as gamma-delta T cells, that can seek out and kill the residual tumor cells. We have leveraged our proprietary genetic modifications of gamma-delta T cells to protect the cells from chemotherapy-induced damage, potentially allowing for their concurrent delivery with chemotherapy. This could potentially enable our product candidates to recognize and kill residual tumor cells, including chemotherapy resistant cells, by attacking at the time when the tumor is experiencing maximum chemotherapy-induced stress and vulnerability. We have termed this approach as our "DeltEx drug resistant immunotherapy," or DeltEx DRI, and it is the basis for several of our programs, including INB-200. We are the first company to advance genetically modified gamma-delta T cells into the clinic. In order to develop an off-the-shelf therapy, we are developing a donor-derived, expanded, activated, non-genetically modified gamma-delta T cell therapeutic candidate for the treatment of leukemia.

Our DeltEx platform is designed to overcome many of the challenges associated with the expansion, genetic engineering and scalable manufacturing of gamma-delta T cells. This approach allows us to expand the cells *ex vivo* to administer a potentially therapeutic dose to patients, harnessing the unique properties of gamma-delta T cells, including their ability to broadly recognize cellular stress signals on tumor cells. We have used our DeltEx platform to create our deep pipeline of innovative allogeneic,

autologous and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

The following chart shows the developmental status of our clinical and preclinical product candidates, all of which are wholly owned:

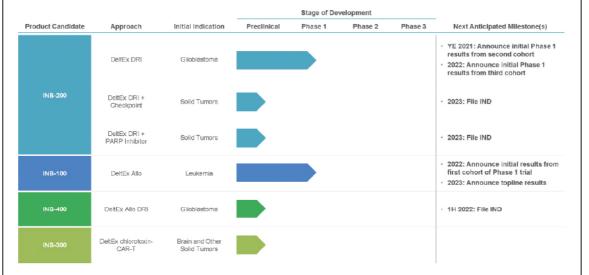


Figure 1. Pipeline Chart

To date, cell therapies utilizing chimeric antigen receptor T cells, or CAR-T cells, while impactful in liquid tumors, have demonstrated limited efficacy in the treatment of solid tumors. The American Cancer Society estimates that there are 1.7 million new solid tumor cases annually in the United States. nine times the rate of blood cancers. This represents a high unmet medical need not adequately addressed by current cell therapies in development. One of our lead product candidates, INB-200, is a genetically modified autologous gamma-delta T cell product candidate in Phase 1 development. Our initial indication is newly diagnosed glioblastoma, or GBM, for which the standard-of-care has been largely unchanged since the implementation of the Stupp regimen, surgical resection followed by radiation and chemotherapy, in 2005. Despite current treatments, the majority of patients relapse within one year, with very few patients surviving beyond five years. We engineered INB-200 to be resistant to alkylating agents, a class of chemotherapeutic drugs used in the treatment of GBM and other cancers. This could allow INB-200 to be administered as an adjuvant to the current standard-of-care in the newly diagnosed treatment setting. In preclinical studies, our DeltEx DRI technology has been shown to maintain immune cell function in toxic chemotherapeutic environments, demonstrating potential to be used concomitantly in combination with chemotherapy for the treatment of multiple solid tumor cancers. We are conducting a Phase 1 repeat dose escalation clinical trial of INB-200 in newly diagnosed GBM patients at the O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham, or UAB. We expect to report initial results from the second cohort in this Phase 1 trial by the end of 2021 and initial Phase 1 results from the third cohort in this Phase 1 trial in 2022.

We are also seeking to develop off-the-shelf DeltEx therapeutic candidates, which has led to our first allogeneic clinical program, INB-100, to demonstrate the safety of donor derived gamma-delta T cells. This therapeutic candidate is in initial development for the treatment of patients with leukemia that are undergoing HSCT. The number of HSCT procedures has been increasing over the last 20 years, with more than 9,000 patients treated in the United States in 2018. Acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL, represent two of the three most common allogeneic HSCT-treated cancers, accounting for approximately 50% of all allogeneic HSCTs. We have developed scalable methods to expand and activate gamma-delta T cells from peripheral blood in an automated manufacturing device. Prior clinical observations have shown that high numbers of circulating gamma-delta T cells have been correlated with improved survival outcomes in HSCT patients. The potential ability of INB-100 to kill residual leukemic cells, coupled with historically observed survival benefits, may

reduce leukemic relapse in HSCT patients. We are conducting a Phase 1 dose-escalation clinical trial of INB-100 in allogeneic HSCT patients at the University of Kansas Cancer Center. We currently expect to report initial data from the first cohort in this trial in 2022, and topline data from all cohorts in 2023.

INB-400 is our first program developing allogeneic DeltEx therapeutic candidates for solid tumor cancers. We plan to utilize clinical data from our ongoing Phase 1 clinical trials of INB-200 and INB-100 to provide the safety data necessary to support submission of an investigational new drug application, or IND, for INB-400, by first half of 2022 to initiate a clinical trial for the treatment of newly diagnosed GBM. INB-300 is our second preclinical program focused on developing DeltEx DRI product candidates with an added CAR.

We are also developing a broad portfolio of preclinical programs focused on expanding the application of our DeltEx platform into other solid tumor types, as well as combinations with other therapies approved by the U.S. Food and Drug Administration, or FDA, to enhance their antitumor activity. We believe that our preclinical data support the development of DeltEx DRI gamma-delta T cells in combination with approved therapies, such as checkpoint inhibitors and inhibitors of DNA damage repair, or DDR, pathways, such as poly (ADP-ribose) polymerase, or PARP, inhibitors. Our future product candidates could incorporate additional proprietary genetic alterations designed to make them resistant to the chemotherapies utilized to treat multiple types of solid tumor cancers.

As of June 30, 2021, our intellectual property portfolio currently consists of seven patent families that broadly protect our DeltEx platform and our product candidates, both through composition of matter and method of use. Our patents broadly cover any genetic modification to gamma-delta T-cells that confers chemotherapy resistance. They also cover the method of generating these genetically engineered cells from patients or donors and their use in multiple solid and liquid tumors. Our portfolio broadly covers the use of allogeneic gamma-delta T cells in HSCT. Finally, we have patent families that cover the composition of our CAR constructs in gamma-delta T cells, specifically in out DeltEx DRI cells, and their use in multiple solid and liquid tumors.

We have assembled a team of experts in the discovery and development of gamma-delta T cell-based therapies. We are led by William Ho, our founder and Chief Executive Officer, who has approximately 20 years of combined experience in the management of biotechnology companies and healthcare finance and investing. Our scientific founder and Chief Scientific Officer, Dr. Lawrence Lamb, is a pioneer in the field of gamma-delta T cell biology and manufacturing, who published the foundational work that identified the potential antileukemic effect of these cells and their association with improved overall survival. Dr. Lamb was the first to describe the cell-type specific expansion of Vd1+ gamma-delta T cells in the 1990s, and his expertise has led the development of our DeltEx platform. Dr. Lamb also chairs our Scientific Advisory Board, which includes a globally renowned group of clinicians, oncologists and immunologists. Patrick McCall, CPA, our Chief Financial Officer, previously served as Vice President of Finance at Turnstone Biologics Inc., where he managed strategic and financial operations and supported investor relations. Dr. Kate Rochlin, our Vice President, Operations and Innovation, is an accomplished scientist and entrepreneur with 14 years of experience in research, development and operations, previously serving as Chief Business Officer at Cambridge-based Curadigm.

#### **Our Strategy**

We are dedicated to leveraging our DeltEx platform to develop next generation cell therapies that we believe can dramatically improve outcomes for cancer patients. To achieve this goal, our strategy is as follows:

- Continue clinical development of our lead product candidates, INB-200 and INB-100.
- Advance INB-400 and INB-300 into clinical development, subject to receiving regulatory authorization to proceed pursuant to INDs.
- Leverage our DeltEx platform for additional indications and product candidates.
- Advance and continue to scale our manufacturing.
- Independently develop and commercialize our product candidates where we believe we can maximize their value and benefit to patients.

#### **Risk Factor Summary**

Our business and our ability to execute our strategy are subject to many risks. Before making a decision to invest in our common stock, you should carefully consider all of the risks and uncertainties described in the section titled "Risk Factors" immediately following this prospectus summary section and all of the other information in this prospectus. These risks include, but are not limited to the following:

- 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.
- Even if this offering is successful, 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 in order 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 in 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 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.

#### **Corporate Information**

Incysus, Ltd. was incorporated in Bermuda on February 8, 2016. On May 7, 2018, Incysus, Ltd. reincorporated in the United States in a domestication transaction in which Incysus, Ltd. converted into a newly formed Delaware corporation, Incysus Therapeutics, Inc. Upon the domestication, each Class A share of Incysus, Ltd. was automatically converted into one share of common stock of Incysus Therapeutics, Inc. and each Class B share of Incysus, Ltd. was automatically cancelled and did not convert into any shares of any class of capital stock of Incysus Therapeutics, Inc. In August 2020, we amended our certificate of incorporation, as amended, to change our name to IN8bio, Inc. Our principal executive offices are located at 79 Madison Avenue, New York, New York 10016, and our telephone number is (646) 600-6438. Our corporate website address is www.in8bio.com. Information contained on, or accessible through, our website is not a part of this prospectus. We have included our website in this prospectus solely as an inactive textual reference.

#### Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and we will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least \$700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financial statements to those of other public companies more difficult. As a result of this election, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests.

We are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250 million

measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. 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 have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

#### The Offering

Common stock to be offered

shares

Common stock to be outstanding after this

shares (or shares if the underwriters exercise their

offering

option to purchase additional shares in full)

Option to purchase additional shares

shares

Use of proceeds

We estimate that the net proceeds from this offering will be approximately \$ million (or approximately \$ underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering, together with our existing cash, as follows:

- approximately \$ to\$ to advance the clinical development of INB-200, including the completion of our ongoing Phase 1 clinical trial and the initiation of a Phase 2 clinical trial for the treatment of newly diagnosed GBM, and for the evaluation of additional indications;
- approximately \$ to \$ to advance the clinical development of INB-100, including the completion of our ongoing Phase 1 clinical trial for the treatment of leukemia patients undergoing HSCT;
- approximately \$ to \$ to advance the clinical development of INB-400, including the IND submission and the initiation of a Phase 1 clinical trial for the treatment of newly diagnosed GBM; and
- the remainder to fund other research and development activities, including preclinical development, development of our manufacturing capabilities, working capital and other general corporate purposes.

See the section titled "Use of Proceeds" for additional information.

Risk factors

You should read the section titled "Risk Factors" for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.

Nasdag Global Market

symbol "INAB"

The number of shares of our common stock to be outstanding after this offering is based on 14,754,553 shares of common stock outstanding as of March 31, 2021, and excludes:

1.552.290 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2021 under our 2018 Equity Incentive Plan, as amended, or the 2018 Plan, with a weighted-average exercise price of \$5.20 per share;

- shares of our common stock issuable upon the exercise of stock options that will be granted to a director upon the completion of this offering pursuant to an antidilution right, as more fully described in the section titled "Certain Relationships and Related Party Transactions—Director Antidilution Rights";
- shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, or the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, plus any future increases in the number of shares of common stock reserved for issuance, as more fully described in the section titled "Executive and Director Compensation—Employee Benefit Plans—2020 Equity Incentive Plan"; and
- shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, plus any future increases, including annual automatic evergreen increases, in the number of shares of common stock reserved for issuance under our ESPP, as more fully described in the section titled "Executive and Director Compensation—Employee Benefit Plans—2020 Employee Stock Purchase Plan."

In addition, unless we specifically state otherwise, the information in this prospectus assumes:

- the filing and effectiveness of our amended and restated certificate of incorporation immediately after the completion of this offering and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 10,990,065 shares of our common stock upon the completion of this offering;
- a 0.365-for-1 reverse stock split of our common stock and preferred stock effected on November 5, 2020;
- · no exercise of the outstanding options described above; and
- no exercise by the underwriters of their option to purchase up to our common stock.

#### **Summary Financial Data**

The following tables set forth a summary of our financial data. We have derived the statement of operations and balance sheet data as of and for the years ended December 31, 2019 and 2020 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations data for the three months ended March 31, 2020 and March 31, 2021 and the balance sheet data as of March 31, 2021 have been derived from unaudited condensed interim unaudited financial statements included elsewhere in this prospectus. Our unaudited condensed interim financial statements were prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, on the same basis as our audited financial statements and include, in the opinion of management, all adjustments, consisting of normal recurring adjustments, that are necessary for the fair presentation of the financial information set forth in those financial statements. Our historical results are not necessarily indicative of the results to be expected for any future periods. The following summary financial data should be read with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

		Years Ended December 31,		Three Months Ended March 31,				
thousands, except share and per share data)		2019	2020		2020		2021	
Statement of Operations Data:								
Operating expenses:								
Research and development	\$	2,358	\$	5,378	\$	1,052	\$	1,245
General and administrative		2,708		3,179		639		1,118
Loss on disposal of property and equipment		68		_		_		_
Total operating expenses		5,134		8,557		1,691		2,363
Loss from operations		(5,134)		(8,557)		(1,691)		(2,363)
Net loss	\$	(5,134)	\$	(8,557)	\$	(1,691)	\$	(2,363)
Net loss attributable to common stockholders <sup>(1)</sup>	\$	(5,912)	\$	(10,340)	\$	(1,951)	\$	(3,069)
Net loss per share attributable to common stockholders: basic and diluted	\$	(1.85)	\$	(3.02)	\$	(0.59)	\$	(0.82)
Weighted-average shares used to compute net loss per share attributable to common stockholders: basic and diluted	3,	188,165	3	,419,075	3,	,305,367		3,764,488
Pro forma net loss attributable to common stockholders <sup>(1)</sup>			\$	(5,134)			\$	(2,363)
Pro forma net loss per share attributable to common stockholders (unaudited): basic and diluted <sup>(1)</sup>			\$	(0.83)			\$	(0.16)
Weighted-average shares used to compute pro forma net loss per share attributable to common stockholders (unaudited): basic and diluted <sup>(1)</sup>			6	,172,715			1	4,754,553

<sup>(1)</sup> The unaudited pro forma basic and diluted weighted-average common stock used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been

prepared to reflect the automatic conversion of all outstanding shares of our convertible preferred stock into common stock upon the completion of this offering.

		As of March 31, 2021					
(in thousands)	Actual	Pro Forma <sup>(1)</sup> (unaudited)	Pro Forma As Adjusted <sup>(2)(3)</sup> (unaudited)				
Balance Sheet Data:		, , , , , ,	, , , , , , , , , , , , , , , , , , , ,				
Cash	\$ 15,052	\$ 15,052	\$				
Working capital <sup>(4)</sup>	12,310	12,310					
Total assets	20,423	20,423					
Preferred stock	34,900	_	_				
Total stockholders' (deficit) equity	(18,581)	16,319					

- (1) The pro forma column reflects the automatic conversion of all of the outstanding shares of our preferred stock into an aggregate of 10,990,065 shares of common stock upon the completion of this offering.
- (2) The pro forma as adjusted column reflects the pro forma adjustments set forth above and the sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of the amount of cash, working capital, total assets and total stockholders' equity by \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease each of cash, working capital, total assets and stockholders' equity by \$ million, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting estimated underwriting discounts and commissions.
- (4) We define working capital as current assets less current liabilities.

#### **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 prospectus, 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.

#### 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 \$5.1 million and \$8.6 million for the years ended December 31, 2019 and 2020, respectively, and \$2.4 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$20.4 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.

Even if this offering is successful, 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.

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. Based on our research and development plans, we believe that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations into 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 in order 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 in particular, including genetic modification and DeltEx DRI gamma-delta T cells, have not been extensively tested over any significant period of time. 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 in particular 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 leukoycte 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 postmarket 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, in order 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 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.

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 gamma-delta T cells 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.

Our gamma-delta T cells and samples 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, we would need to establish replacement cell banks, which could impact clinical supply and could delay our clinical trials. We would need another supplier with a GMP facility, available supply and would need to potentially conduct additional animal studies to determine equivalence of the vector. If we or our third-party contractors are unable to establish replacement cell banks, cells, samples and vectors, as applicable, we could 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 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 thirdparty 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 and will continue to be able to do so after the completion of this offering. 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 highquality 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 this offering and/or 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 March 31, 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 this Offering and Ownership of Our Common Stock

No public market for our common stock currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common stock. If an active trading market for our common stock does not develop following this offering, 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 initial public offering price of our common stock will be determined by negotiations between us and the representative of the underwriters and may not be indicative of the market prices of our common stock that will prevail in the trading market.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering and may subject us to securities litigation suits.

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. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, 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 of 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 March 31, 2021, and upon the completion of this offering and without giving effect to any purchases in this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing % of our outstanding common stock (or % if the underwriters exercise in full their option to purchase additional shares to cover overallotments, if any). If our executive officers, directors and stockholders who owned 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, including investors in this offering, 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 in this offering.

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. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of June 30, 2021, and assuming no exercise of the underwriters' overallotment option. This includes the shares that we are selling in this offering, 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 but will be able to be sold after the offering, as further described in the sections titled "Shares Eligible for Future Sale" and "Underwriting" herein. Moreover, upon the completion of this offering, 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 described in the section titled "Underwriting" herein.

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

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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, which will become effective immediately after the completion of this offering, 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 after the completion of this offering, 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 have broad discretion in the use of our cash resources, including the net proceeds from this offering, and may use them ineffectively, in ways with which you do not agree or in ways that do not increase the value of your investment.

Our management will have broad discretion in the application of our cash, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in additional operating losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled "Use of Proceeds" herein for additional information.

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 will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be 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.

Upon the completion of this offering, we will become 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.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" and elsewhere in this prospectus, regarding, among other things:

- our plans to develop and commercialize our product candidates:
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- our ability to take advantage of abbreviated regulatory pathways for any of our product candidates:
- our expectations regarding the impact of the ongoing COVID-19 pandemic on our business, our industry and the economy;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms:
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our continued reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates:
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- · our ability to compete in the markets we serve;
- the impact of government laws and regulations and liabilities thereunder;
- our expected use of proceeds from this offering;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- · developments relating to our competitors and our industry; and
- · other factors that may impact our financial results.

The foregoing list of risks is not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors

on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

#### MARKET AND INDUSTRY DATA

Certain market and industry data included in this prospectus were obtained from market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of the market and industry data used in this prospectus involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from the industry publications and other third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

#### **USE OF PROCEEDS**

We estimate that the net proceeds to us from this offering will be approximately \$\\$\text{million}\$ if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of \$\\$\text{per share}, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us from this offering by \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us, would increase or decrease the net proceeds to us by \$ million, assuming the assumed initial public offering price per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

We intend to use the net proceeds from this offering, together with our existing cash, as follows:

- approximately \$ to \$ to advance the clinical development of INB-200, including the completion of our ongoing Phase 1 clinical trial and the initiation of a Phase 2 clinical trial for the treatment of newly diagnosed GBM, and for the evaluation of additional indications;
- approximately \$ to \$ to advance the clinical development of INB-100, including the completion of our ongoing Phase 1 clinical trial for the treatment of leukemia patients undergoing HSCT;
- approximately \$ to \$ to advance the clinical development of INB-400, including the IND submission and the initiation of a Phase 1 clinical trial for the treatment of newly diagnosed GBM; and
- the remainder to fund other research and development activities, including preclinical development, development of our manufacturing capabilities, working capital and other general corporate purposes.

We may also use a portion of the net proceeds from this offering designated for working capital and general corporate purposes, or to in-license, acquire or invest in complementary businesses, technologies, products or assets. Although we currently have no agreements, commitments or obligations to do so, we evaluate such opportunities and engage in related discussions with third parties from time to time.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our ongoing and planned clinical trials, our ability to take advantage of expedited programs or to obtain regulatory approval for product candidates, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our research and development plans, we believe that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations into . 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.

We do not anticipate that the expected net proceeds from this offering, together with our existing cash, will be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. Because the time and costs to complete development of our product candidates will depend on the results of future preclinical studies and clinical trials and discussions with and decisions by regulatory authorities, we cannot reasonably estimate the amount of additional capital we will require to complete development. In particular, the cost and timing of completing development of any product candidate will vary widely depending on the outcome of ongoing and future preclinical studies and clinical trials, as well as future guidance from regulatory authorities as to the number, scope and design of clinical trials that will be necessary to support regulatory applications.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

#### **DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business.

#### **CAPITALIZATION**

The following table sets forth our cash and our capitalization as of March 31, 2021 on:

- an actual basis;
- a pro forma basis, to reflect the automatic conversion of all of the outstanding shares of our preferred stock into an aggregate of 10,990,065 shares of common stock upon the completion of this offering; and
- a pro forma as adjusted basis, giving effect to the pro forma adjustments discussed above, and giving further effect to (i) the sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the filing and effectiveness of our amended and restated certificate of incorporation.

You should read this table together with the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	As of March 31, 2021		
(in thousands, except share and per share amounts)	Actual	Pro Forma	Pro Forma As Adjusted <sup>(1)</sup>
Cash	\$ 15,052	\$ 15,052	\$
Convertible preferred stock, Series A, par value, \$0.0001 per share; 27,564,260 shares authorized, 9,993,727 shares issued and outstanding, actual; 27,564,260 shares authorized and no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	\$ 34,900	* —	
Stockholders' (deficit) equity:			
Preferred stock, par value \$0.0001 per share; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	_	_	
Common stock, par value \$0.0001 per share; 50,700,000 shares authorized, 3,764,488 shares issued and outstanding, actual; 50,700,000 shares authorized and 14,754,553 shares issued and outstanding, pro forma; 490,000,000 shares authorized and shares issued and outstanding, pro forma as adjusted	1	1	
Additional paid-in capital	1,819	36,719	
Accumulated deficit	(20,401)	(20,401)	
Total stockholders' (deficit) equity	(18,581)	16,319	
Total capitalization	\$ 16,319	\$ 16,319	\$

<sup>(1)</sup> Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of pro forma as adjusted cash, additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease each of pro forma as adjusted cash, additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions. See above comment about sensitivity.

The foregoing discussion and tables above are based on 3,764,488 shares of common stock outstanding as of March 31, 2021, and excludes as of such date:

- 1,552,290 shares of our common stock issuable upon the exercise of outstanding stock options under our 2018 Plan as of March 31, 2021, with a weighted-average exercise price of \$5.20 per share;
- shares of our common stock issuable upon the exercise of stock options that will be granted to a director upon the completion of this offering pursuant to an antidilution right, as more fully described in the section titled "Certain Relationships and Related Party Transactions—Director Antidilution Rights";
- shares of our common stock reserved for future issuance under the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2020 Plan; and
- shares of our common stock reserved for future issuance under our ESPP, which
  will become effective immediately prior to the execution of the underwriting agreement related
  to this offering, as well as any future increases in the number of shares of common stock
  reserved for issuance under our ESPP.

#### **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book deficit as of March 31, 2021 was \$23.3 million, or \$(6.20) per share of our common stock. Our historical net tangible book deficit represents our total tangible assets less total liabilities and preferred stock. Historical net tangible book deficit per share is our historical net tangible book deficit divided by the number of shares of our common stock outstanding as of March 31, 2021

Our pro forma net tangible book value as of March 31, 2021 was \$11.6 million, or \$0.78 per share of our common stock, based on the total number of shares of our common stock outstanding as of March 31, 2021. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to the automatic conversion of all of the outstanding shares of our preferred stock into an aggregate of 10,990,065 shares of common stock upon the completion of this offering.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$
Historical net tangible book deficit per share as of March 31, 2021	\$ (6.20)	
Pro forma increase in net tangible book value per share as of March 31, 2021	• •	
attributable to the pro forma transactions described above	6.98	
Pro forma net tangible book value per share as of March 31, 2021	0.78	
Increase in pro forma net tangible book value per share attributable to new		
investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted net tangible book value per share after this offering by \$ per share and the dilution per share to new investors participating in this offering by \$ assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 1.0 million shares of common stock offered by us would increase the pro forma as adjusted net tangible book value after this offering by \$ per share and decrease the dilution per share to new investors participating in this offering by \$ per share, and a decrease of 1.0 million shares of common stock offered by us would decrease the pro forma as adjusted net tangible book value by \$ share, and increase the dilution per share to new investors in this offering by \$ per share. assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise in full their option to purchase up to additional shares of common stock from us, the pro forma as adjusted net tangible book value per share after giving effect

to this offering would be \$ per share, representing an immediate increase to existing stockholders of \$ per share, and dilution to new investors participating in this offering of \$ per share.

The following table summarizes on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us on an as converted basis, the total consideration paid and the weighted-average price per share paid by existing stockholders and by investors purchasing shares in this offering at the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page on this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Total Shares Purchased Consideration			ion	Average Price Per
	Number	Percent	Amount	Percent	Share
Existing stockholders  New investors	14,754,553	75.9%	\$35,559,158	32.2%	\$ 2.41
Total		%	\$	%	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, an increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the assumed initial public offering price remains the same.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding upon the completion of this offering.

The foregoing discussion and tables above are based on 3,764,488 shares of common stock outstanding as of March 31, 2021, and excludes:

- 1,552,290 shares of our common stock issuable upon the exercise of outstanding stock options under the 2018 Plan as of December 31, 2020, with a weighted-average exercise price of \$5.20 per share;
- shares of our common stock issuable upon the exercise of stock options that will be granted to a director upon the completion of this offering pursuant to an antidilution right, as more fully described in the section titled "Certain Relationships and Related Party Transactions—Director Antidilution Rights";
- shares of our common stock reserved for future issuance under the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our 2020 Plan; and
- shares of our common stock reserved for future issuance under our ESPP, which
  will become effective immediately prior to the execution of the underwriting agreement related
  to this offering, as well as any future increases in the number of shares of common stock
  reserved for issuance under our ESPP.

To the extent that any outstanding options or warrants are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements.

#### 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 gammadelta 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 vivoexpanded 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 cohort in this Phase 1 trial by the end of 2021 and initial Phase 1 results from the third cohort 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 topline results for all cohorts 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 in the first half of 2022 and in 2023.

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. Since inception, we have 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 \$5.1 million, \$8.6 million and \$2.4 million for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of \$20.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our ongoing activities.

We anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public

company following the completion of this offering. We expect that our expenses and capital requirements 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.

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.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements through . 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" below.

#### COVID-19

The ongoing COVID-19 pandemic, which began in December 2019 and has spread worldwide, may continue to affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trials or future clinical trials or the progress or completion of our ongoing clinical trials, disrupt regulatory activities, or have other adverse effects on our business, results of operations, and financial condition. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations and our ability to raise additional funds to support our operations.

We are continuing to monitor the potential impact of the COVID-19 pandemic on our business and financial statements. From December 2020 through February 2021, we experienced delays in additional patient enrollment in both of our ongoing Phase 1 trials due to the second surge of the COVID-19 pandemic. In our INB-100 trial for leukemia patients, due to the risks of potential donor COVID-19 infection, making HSCs unavailable to patients who are undergoing a myeloablative process, necessitated a modification to our clinical protocol. We submitted a protocol modification to the FDA and IRB in January 2021, and as of February 2021, we were cleared to re-initiate enrollment of patients in the INB-100 trial. We are following, and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention as well as federal, state, and local governments regarding working-from-home practices for non-essential employees as well as return-to-work policies and procedures. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic.

We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business, and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

#### **Components of Our Results of Operations**

#### Revenue

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

### **Operating Expenses**

Research and Development Expenses

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

- employee-related expenses, including salaries, related-benefits 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 Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; 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 in the near-term as we continue to build a team to support our administrative, accounting and finance, communications, legal and business development efforts. Following this offering, we expect to incur increased expenses

associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services; director and officer insurance costs; and investor and public relations costs.

# **Results of Operations**

# Comparison of the Three Months Ended March 31, 2020 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2021:

	Three Months En	Three Months Ended March 31,		
	2020	2021	Change	
	(in thousands)			
Operating expenses:				
Research and development	\$ 1,052	\$ 1,245	\$ 193	
General and administrative	639	1,118	479	
Total operating expenses	1,691	2,363	672	
Loss from operations	(1,691)	(2,363)	(672)	
Net loss	\$(1,691)	\$(2,363)	\$(672)	

# Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2020 and 2021:

	Three Months En		
	2020	2021	Change
	(in thous		
Direct research and development expenses:			
INB-100	\$ 102	\$ 67	\$ (35)
INB-200	3	7	4
Unallocated expenses			
Preclinical	291	166	(125)
Personnel expenses <sup>(1)</sup>	439	712	273
Facility related and other	217	293	76
Total research and development expenses	\$1,052	\$1,245	\$ 193

<sup>(1)</sup> Includes stock-based compensation of \$16,000 and \$0.2 million, respectively.

Research and development expenses were \$1.2 million for the three months ended March 31, 2021, compared to \$1.0 million for the three months ended March 31, 2020. The increase of \$0.2 million was primarily a result of higher personnel-related costs due to an increase in stock-based compensation expense.

#### General and Administrative Expenses

General and administrative expenses were \$1.1 million for the three months ended March 31, 2021, compared to \$0.6 million for the three months ended March 31, 2020. The increase of \$0.5 million was primarily a result of higher personnel-related costs due to an increase in stock-based compensation expense.

#### Comparison of the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020:

	Year ended De	Year ended December 31,			
	2019	2019 2020			
	(in thous	(in thousands)			
Operating expenses:					
Research and development	\$ 2,358	\$ 5,378	\$ 3,020		
General and administrative	2,708	3,179	471		
Loss on disposal of equipment	68	_	(68)		
Total operating expenses	5,134	8,557	3,423		
Loss from operations	(5,134)	(8,557)	(3,423)		
Net loss	\$(5,134)	\$(8,557)	\$(3,423)		

#### Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020:

	Year ended D	Year ended December 31,		
	2019	2019 2020		
	(in thou			
Direct research and development expenses:				
INB-100	\$ —	\$ 706	\$ 706	
INB-200	_	689	689	
Unallocated expenses				
Preclinical	595	1,319	724	
Personnel expenses <sup>(1)</sup>	1,144	1,687	543	
Facility related and other	619	977	358	
Total research and development expenses	\$2,358	\$5,378	\$3,020	

<sup>(1)</sup> Includes stock-based compensation of \$0.2 million.

Research and development expenses were \$2.4 million for the year ended December 31, 2019, compared to \$5.4 million for the year ended December 31, 2020. The increase of \$3.0 million was primarily due to \$1.4 million for the continued development and the advancement of INB-100 and INB-200 into Phase 1 clinical trials, \$0.7 million in preclinical expenses related to additional reagents and laboratory supplies in preparation of any additional impacts of the ongoing COVID-19 pandemic on our operations and supply chains, \$0.5 million in personnel expenses which was primarily due to an increase in stock-based compensation expense, and \$0.4 million in facility and other expenses related to office space.

# General and Administrative Expenses

General and administrative expenses were \$2.7 million for the year ended December 31, 2019, compared to \$3.2 million for the year ended December 31, 2020. The increase of \$0.5 million was primarily due to increased personnel expenses of \$0.4 million and other expenses of \$0.1 million.

# **Liquidity and Capital Resources**

To date we have funded our operations primarily through the sale of equity and equity-linked securities. Through March 31, 2021, we have raised an aggregate of \$35.6 million of gross proceeds from the sale of our securities. As of March 31, 2021, we had cash of \$15.1 million. Our net loss was \$5.1 million, \$8.6 million and \$2.4 million for the years ended December 31, 2019 and 2020 and the three

months ended March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of \$20.4 million. Since our inception, we have not generated any revenue from product sales and have incurred significant operating 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. Since our inception, we have incurred losses and negative cash flows from operations and expect these conditions to continue for the foreseeable future.

#### Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year ended December 31,		Three Months Ended March 31,	
	2019	2019 2020		2021
	(in thousands)		(in thousands)	
Net cash used in operating activities	\$(4,801)	\$ (7,133)	\$(1,623)	\$(2,507)
Net cash provided by investing activities	356	_	_	_
Net cash provided by (used in) financing activities	65	24,517	5,680	(435)
Net (decrease) increase in cash and restricted cash	\$(4,380)	\$17,384	\$ 4,057	\$(2,942)

#### Operating Activities

During the three months ended March 31, 2020, net cash used in operating activities was \$1.6 million, primarily due to our net loss of \$1.7 million offset by an increase of \$0.1 million in prepaid expenses and other current assets.

During the three months ended March 31, 2021, net cash used in operating activities was \$2.5 million, primarily due to our net loss of \$2.4 million and decrease in our operating assets and liabilities of \$0.7 partially offset by increases in non-cash charges of \$0.5 million. Decreases in our operating assets and liabilities consisted primarily of \$0.3 million in accrued expenses and other current liabilities, \$0.2 million increase in accounts payable and a decrease of \$0.1 million in prepaid expenses and other current assets. Increases in our non-cash charges consisted primarily of \$0.4 million in stock-based compensation.

During the year ended December 31, 2019, net cash used in operating activities was \$4.8 million, primarily due to our net loss of \$5.1 million partially offset by increases in our operating assets and liabilities of \$0.3 million. Increases in our operating assets and liabilities consisted primarily of \$0.1 million prepaid expenses, \$0.1 million other current assets, and \$0.1 million increase in accounts payable and accrued expenses and other current liabilities of \$0.1 million.

During the year ended December 31, 2020, net cash used in operating activities was \$7.1 million, primarily due to our net loss of \$8.6 million partially offset by increases in our operating assets and liabilities of \$0.6 million and increases in non-cash charges of \$0.9 million. Increases in our operating assets and liabilities consisted primarily of \$0.8 million in accrued expenses and other current liabilities offset by a \$0.2 million decrease in accounts payable. Increases in our non-cash charges consisted primarily of \$0.4 million in stock-based compensation, \$0.4 million in non-cash common stock issuances, and \$0.1 million in depreciation.

#### Investing Activities

There were no investing activities during the three months ended March 31, 2020 and 2021.

Net cash provided by investing activities during the year ended December 31, 2019 was \$0.4 million, primarily due to \$0.7 million for the disposal of property and equipment, partially offset by \$0.3 million for the purchase of property and equipment.

There were no investing activities during the year ended December 31, 2020.

# Financing Activities

During the three months ended March 31, 2020, net cash provided by financing activities was \$5.7 million primarily due to the sale of Series A Preferred Stock.

During the three months ended March 31, 2021, net cash used by financing activities was \$0.4 million from the payment of deferred offering costs and payment of financing lease obligations.

During the year ended December 31, 2019, net cash provided by financing activities was \$0.1 million from the proceeds of the exercise of employee stock options.

During the year ended December 31, 2020, net cash provided by financing activities was \$24.5 million primarily due to the sale of Series A 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. In addition, we expect to incur additional costs associated with operating as a public company following the completion of this offering. 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. As of March 31, 2021, we had cash of \$15.1 million. Based on our research and development plans, we believe that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations

. 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.

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**

The following table summarizes our contractual obligations and commitments as of December 31, 2020:

Payments Due by Period					
Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	
	(in thousands)				
\$2,266	\$832	\$1,157	\$ 277	\$	
\$2,266	\$832	\$1,157	\$ 277	\$ —	
	\$2,266	Total Less than 1 Year (ii \$2,266 \$832	Total Less than 1 to 3 Years (in thousands \$2,266 \$832 \$1,157	Total         Less than 1 Year         1 to 3 Years         4 to 5 Years           (in thousands)         \$2,266         \$832         \$1,157         \$ 277	

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

#### Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

#### Research and Development Costs

We expense all costs in performing research and development activities in the periods in which they are incurred. Research and development expenses include salaries and benefits, stock-based

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

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

#### Stock-Based Compensation

We account for our stock-based compensation as expense in the statements of operations based on the awards' grant date fair values. We account for forfeitures as they occur by reversing any expense recognized for unvested awards.

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

# Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the option grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

the prices at which we sold shares of preferred stock and the superior rights and preferences
of the preferred stock relative to our common stock at the time of each grant;

- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- · our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or sale of our company in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Following the completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock on the date of option grant.

#### **Options Granted**

The following table sets forth, by grant date, the number of shares subject to options granted from January 1, 2020 through the date of this prospectus, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options:

Grant Date	Number of Common Shares Subject to Options Granted	Exercise Price per Common Share	Estimated Per-Share Fair Value of Options	Estimated Fair Value per Common Share at Grant Date
February 3, 2020	1,825	\$1.10	\$0.96	\$1.10
May 5, 2020	28,287	\$1.23	\$0.96	\$1.23
October 5, 2020	896,628	\$6.74	\$4.79	\$6.74
October 15, 2020	3,066	\$6.74	\$4.79	\$6.74
February 1, 2021	305,132	\$5.36	\$4.02	\$5.36

# **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

#### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements appearing elsewhere in this prospectus.

# **Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of March 31, 2021, we had cash of \$15.1 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates but is minimal. We have not entered into investments for trading or speculative purposes.

#### **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits that an "emerging growth company" may take advantage of the extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use the extended transition period under the JOBS Act. Accordingly, our financial statements may not be comparable to the financial statements of public companies that comply with such new or revised accounting standards. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least \$700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

#### **BUSINESS**

#### 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 gammadelta 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 vivoexpanded 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 cohort in this Phase 1 trial by the end of 2021 and initial Phase 1 results from the third cohort 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 topline results for all cohorts 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 in the first half of 2022 and in 2023.

Chemotherapy, a mainstay of solid tumor treatment, can deplete and damage immune cells, limiting their ability to seek and kill tumors. Despite these limitations, chemotherapy continues to be used in standard-of-care regimens because of its ability to directly kill tumors. However, residual tumor cells, which are chemotherapy resistant, often remain and lead to disease recurrence. This is further compounded by the lymphodepleting properties of chemotherapy, which can severely reduce the number of immune cells, such as gamma-delta T cells, that can seek out and kill the residual tumor cells. We have leveraged our proprietary genetic modifications of gamma-delta T cells to protect the cells from chemotherapy-induced damage, potentially allowing for their concurrent delivery with chemotherapy. This could potentially enable our candidates to recognize and kill residual tumor cells, including chemotherapy resistant cells, by attacking at the time when the tumor is experiencing maximum chemotherapy-induced stress and vulnerability. We have termed this approach as our "DeltEx drug resistant immunotherapy," or DeltEx DRI, and it is the basis for several of our programs, including INB-200. We are the first company to advance genetically modified gamma-delta T cells into the clinic. In order to develop an off-the-shelf therapy, we are testing the safety of a donor-derived, expanded, activated, non-genetically modified gamma-delta T cell therapeutic candidate for the treatment of leukemia.

Our DeltEx platform is designed to overcome many of the challenges associated with the expansion, genetic engineering and scalable manufacturing of gamma-delta T cells. This approach allows us to expand the cells *ex vivo* to administer a potentially therapeutic dose to patients, harnessing the unique properties of gamma-delta T cells, including their ability to broadly recognize cellular stress signals on tumor cells. We have used the DeltEx platform to create our deep pipeline of innovative allogeneic, autologous and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

The following chart shows the developmental status of our clinical and preclinical product candidates, all of which are wholly owned:

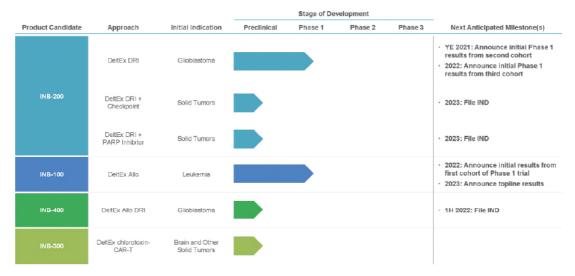


Figure 1. Pipeline Chart

To date, cell therapies utilizing chimeric antigen receptor T cells, or CAR-T cells, while impactful in liquid tumors, have demonstrated limited efficacy in the treatment of solid tumors. The American Cancer Society estimates that there are 1.7 million new solid tumor cases annually in the United States, nine times the rate of blood cancers. This represents a high unmet medical need not adequately addressed by current cell therapies in development. One of our lead candidates, INB-200, is a genetically modified autologous gamma-delta T cell product candidate in Phase 1 development. Our initial indication is newly diagnosed glioblastoma, or GBM, for which the standard-of-care has been largely unchanged since the implementation of the Stupp regimen, surgical resection followed by radiation and chemotherapy, in 2005. Despite current treatments, the majority of patients relapse within one year, with very few patients surviving beyond five years. We engineered INB-200 to be resistant to alkylating agents, a class of chemotherapeutic drugs used in the treatment of GBM and other cancers. This could allow INB-200 to be administered as an adjuvant to the current standard-of-care in the newly diagnosed treatment setting. In preclinical studies, our DeltEx DRI technology has been shown to maintain immune cell function in toxic chemotherapeutic environments, demonstrating potential to be used concomitantly in combination with chemotherapy for the treatment of multiple solid tumor cancers. We are conducting a Phase 1 repeat dose escalation clinical trial of INB-200 in newly diagnosed GBM patients at the O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham, or UAB. We expect to report the initial results from the second cohort in this Phase 1 trial by the end of 2021.

We are also seeking to develop off-the-shelf DeltEx therapeutic candidates, which has led to our first allogeneic clinical program, INB-100, to demonstrate the safety of donor derived gamma-delta T cells. This therapeutic candidate is in initial development for the treatment of patients with leukemia that are undergoing HSCT. The number of HSCT procedures has been increasing over the last 20 years, with more than 9,000 patients treated in the United States in 2018. Acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL, represent two of the three most common allogeneic HSCT-treated cancers, accounting for approximately 50% of all allogeneic HSCTs. We have developed scalable methods to expand and activate gamma-delta T cells from peripheral blood in an automated manufacturing device. Prior clinical observations have shown that high numbers of circulating gamma-delta T cells have been correlated with improved survival outcomes in HSCT patients. The potential ability of INB-100 to kill residual leukemic cells, coupled with historically observed survival benefits, may reduce leukemic relapse in HSCT patients. We are conducting a Phase 1 dose-escalation clinical trial of INB-100 in allogeneic HSCT patients at the University of Kansas Cancer Center. We currently expect to report initial data from the first cohort in this trial in 2022, and topline data from all cohorts in 2023.

INB-400 is our first program developing allogeneic DeltEx therapeutic candidates for solid tumor cancers. We plan to utilize clinical data from our ongoing Phase 1 clinical trials of INB-200 and INB-100 to provide the safety data necessary to support submission of an investigational new drug application, or IND, for INB-400, by first half of 2022 to initiate a clinical trial for the treatment of newly diagnosed GBM. INB-300 is our second preclinical program focused on developing DeltEx DRI product candidates with an added CAR, for which we expect to target certain brain tumors and other solid tumor cancers.

We are also developing a broad portfolio of preclinical programs focused on expanding the application of our DeltEx platform into other solid tumor types, as well as combinations with other therapies approved by the U.S. Food and Drug Administration, or FDA, to enhance their antitumor activity. We believe that our preclinical data support the development of DeltEx DRI gamma-delta T cells in combination with approved therapies, such as checkpoint inhibitors and inhibitors of DNA damage repair, or DDR, pathways, such as poly (ADP-ribose) polymerase, or PARP, inhibitors. Our future product candidates could incorporate additional proprietary genetic alterations designed to make them resistant to the chemotherapies utilized to treat multiple types of solid tumor cancers.

As of June 30, 2021, our intellectual property portfolio currently consists of seven patent families that broadly protect our DeltEx platform and our product candidates, both through composition of matter and method of use. Our patents broadly cover any genetic modification to gamma-delta T-cells that confers chemotherapy resistance. They also cover the method of generating these genetically engineered cells from patients or donors and their use in multiple solid and liquid tumors. Our portfolio broadly covers the use of allogeneic gamma-delta T cells in HSCT. Finally, we have patent families that cover the composition of our CAR constructs in gamma-delta T cells, specifically in our DeltEx DRI cells, and their use in multiple solid and liquid tumors.

We have assembled a team of experts in the discovery and development of gamma-delta T cell-based therapies. We are led by William Ho, our founder and Chief Executive Officer, who has 20 years of combined experience in the management of biotechnology companies and healthcare finance and investing. Our scientific founder and Chief Scientific Officer, Dr. Lawrence Lamb, a pioneer in the field of gamma-delta T cell biology and manufacturing, published the foundational work that identified the potential antileukemic effect of these cells and their association with improved overall survival. Dr. Lamb was the first to describe the cell-type specific expansion of Vd1+ gamma-delta T cells in the 1990s, and his expertise has led to the development of our DeltEx platform. Dr. Lamb also chairs our Scientific Advisory Board, which includes a globally renowned group of clinicians, oncologists and immunologists. Patrick McCall, CPA, our Chief Financial Officer, previously served as Vice President of Finance at Turnstone Biologics Inc., where he managed strategic and financial operations and supported investor relations. Dr. Kate Rochlin, our Vice President, Operations and Innovation, is an accomplished scientist and entrepreneur with 14 years of experience in research, development and operations, previously serving as Chief Business Officer at Cambridge-based Curadigm.

#### **Our Strategy**

We are dedicated to leveraging our DeltEx platform to develop next generation cell therapies that we believe can dramatically improve outcomes for cancer patients. To achieve this goal, our strategy is as follows:

- Continue advancing our lead clinical product candidates, INB-200 and INB-100. INB-200 is our lead autologous DeltEx DRI program that we are initially developing for the treatment of newly diagnosed GBM. We are conducting an ongoing Phase 1 repeat dose escalation clinical trial at the O'Neal Comprehensive Cancer Center at UAB. We expect to report initial results from the second cohort in this Phase 1 trial by the end of 2021. We are also conducting a Phase 1 dose escalation clinical trial of INB-100, our allogeneic DeltEx product candidate in allogeneic HSCT patients, from which we currently expect to report initial results from the first cohort in 2022 and topline results from all cohorts in 2023.
- Advance INB-400 and INB-300 into clinical development, subject to receiving
  authorization from FDA pursuant to INDs. We plan to submit an IND for INB-400, our first
  allogeneic DeltEx DRI therapy for solid tumors, in the first half of 2022. We intend to leverage
  the clinical data from our ongoing Phase 1 clinical trials, INB-200 and INB-100, to provide the

- safety data necessary to support the IND submission in newly diagnosed GBM. INB-300 is a DeltEx DRI with a chlorotoxin CAR, for which a construct has been created and we are testing its ability to kill various tumors in preclinical studies.
- Leverage our DeltEx platform for additional indications and product candidates. We
  will continue to advance internal research including the application of our proprietary DeltEx
  DRI approach into additional solid tumor indications. We are also developing additional
  discovery programs that could incorporate additional proprietary genetic modifications in our
  DeltEx platform designed to address both solid and liquid tumors. We expect to submit three
  additional INDs using INB-200 in combination with other therapeutics for cancer over the next
  few years.
- Advance and continue to scale our manufacturing. We have established an automated, closed-system, reproducible, scalable manufacturing platform. We will continue to focus on expanding manufacturing capacity and capabilities to support our ongoing and anticipated clinical development. In addition to using collaborators and contract manufacturers, we plan to build internal manufacturing capabilities as we demonstrate clinical proof-of-concept, leveraging our company know-how and collaborators for product delivery, logistics and capacity expansion across our parallel processes.
- Independently develop and commercialize our product candidates where we believe we
  can maximize their value and benefit to patients. Given the broad applicability of our
  DeltEx technology pipeline across multiple solid and liquid tumor indications, we plan to
  maximize its value by retaining development and commercialization rights to the product
  candidates, indications and geographies that we believe we can commercialize successfully
  on our own, pending regulatory approval. We plan to collaborate on candidates that show
  promising utility in disease indications, patient populations or geographies that we believe
  would be better served by the resources, specific expertise or commercial abilities of other
  biopharmaceutical companies or partners.

# Gamma-Delta T Cells: Leveraging the Nexus of the Immune System

#### The Rise of Cell Therapy

There has been significant recent innovation in the treatment of cancer, including novel biological and cell therapies. Immuno-oncology, utilizes the immune system to identify and kill cancer cells. Such therapies can either prevent the tumor's ability to suppress immune attack or to directly utilize immune cells to target and kill cancer cells. The immune system consists of complex and highly evolved cells that have the ability to target dangerous pathogens and damaged or sick tissue to keep the body safe. The system is generally comprised of two functional branches, the innate and the adaptive. The innate immune system consists of natural killer, or NK cells, dendritic and other cell types, and is the first line of defense for the body. It mobilizes rapidly and alerts other elements of the immune system so that they can become active. The innate immune system is primarily activated by broadly-expressed stress signals caused by pathogen invasion, tissue damage or cellular transformation. Once the innate immune system has been activated, chemokine signaling orchestrates the interaction between the innate and adaptive immune systems to send effector cells to seek out and destroy specific antigens and the cells that express them. The adaptive immune system is primarily comprised of alpha-beta T cells and B cells that deepen and narrow the response to the specific peptide or antibody target. The adaptive immune response is specific and potent with the ability to provide long-lasting immune memory.

The innate and adaptive immune responses both play critical roles in the fight against cancer. While both systems possess critical functions, the most effective tumor killing occurs when they work in concert. As shown in Figure 2 below, gamma-delta T cells sit at the nexus of the two systems and possess a powerful combination of both innate and adaptive cell properties. They can directly kill without previous antigen priming similar to certain innate cells, such as NK cells, but can also function to present antigen directly to drive cytokine release and to target neoantigens through antigen mediated cell killing. Gamma-delta T cells are endowed with at least two independent recognition systems to sense tumor cells and to initiate anticancer killing by recruiting and activating multiple immune cell types.

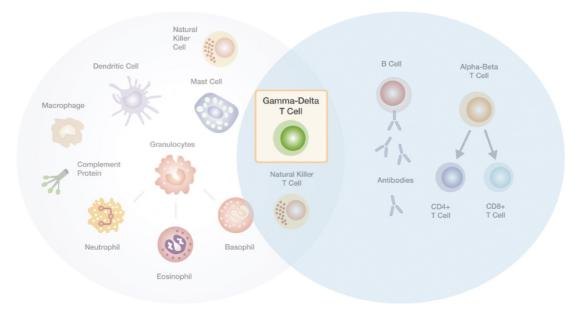


Figure 2. Gamma-Delta T Cells: Innate and Adaptive Immune System Characteristics

Cellular immunotherapy is a type of immuno-oncology therapy whereby human immune cells are enhanced to boost immune function to fight cancer. These cells can be unmodified or genetically modified to enhance some aspect of tumor recognition, binding or the direct killing of cancer cells. Most cell therapy approaches utilize either the adaptive immune system, such as alpha-beta T cells, or the innate immune system, such as NK cells. These approaches have certain inherent limitations, particularly against solid tumors. We believe that gamma-delta T cell therapeutics can overcome many of these challenges due to their unique properties and role across both sides of the immune system.

#### Inherent Limitations of Current Cell Therapy Approaches

A common approach in cell therapy involves the use of genetically engineered CARs on a T or NK cell that enable it to recognize a specific protein or antigen that may be present on the surface of tumor cells. The CAR bypasses the normal biology of T and NK cells, by driving their activation through the binding of the CAR-directed antigen. While effective for direct antigen recognition, the inherent heterogeneity of solid tumors means that it is unlikely that any single antigen will be expressed by all tumor cells.

Since 2017, FDA has approved five autologous CAR-T cell therapies, Kymriah®, Yescarta®, Breyanzi®, Abecma® and Tecartus®, which have been transformative in the treatment of liquid tumors, but CAR-Ts have had extremely limited efficacy in solid tumors to date. This lack of efficacy in solid tumors underscores the inherent challenges of CAR-T approaches. Many of the limitations of CAR-T cell therapies are related to the fundamental dynamics of solid tumors and T cell biology. This includes (i) the potential inability to effectively target the entire tumor using a single antigen CAR due to tumor heterogeneity, (ii) the potential inability to effectively penetrate the tumor microenvironment, or TME, due to physical barriers such as tumor bulk, (iii) the lack of tumor antigens, which are ubiquitously and uniquely expressed on tumor cells, (iv) potential limited T cell function due to the immunosuppressive TME, including regulatory T cells, or Tregs, and other immune-suppressive cells, (v) limited ability to efficiently deliver cells directly to the tumor site, and (vi) the inability to combine with effective chemotherapeutic regimens due to the chemosensitivity of immune cells. Additional challenges that have potentially hampered widespread adoption of existing CAR-T technologies include scalability, safety and cost.

In recent years, there has been increasing focus on CAR-NK cell therapies, with multiple programs currently in development. NK cells are innate immune cells that possess the ability to detect and kill cancer cells by recognizing common antigens without highly selective adapted receptors towards specific

antigens. Their cytotoxicity is mainly dependent on the balance between activating and inhibitory signals, such as killer cell immunoglobulin-like receptors, or KIRs, which can be overcome with the addition of CARs to allow for their use in cell therapy. CAR-NKs are attractive over alpha-beta CARs for two primary reasons: (i) CAR-NKs do not express the cytokine IL-6, which is one of the major drivers of cytokine release syndrome, or CRS, which can lead to substantial morbidity as well as patient deaths, and (ii) CAR-NKs are not major histocompatibility complex, or MHC, restricted and can be infused from a donor to a patient without complex and expensive genetic engineering to prevent graft versus host disease, or GvHD.

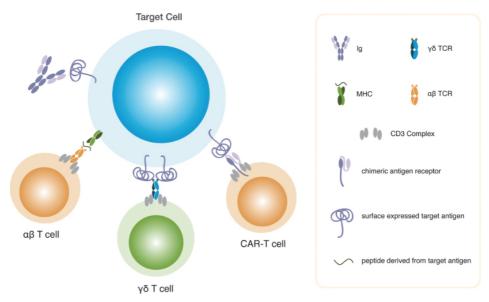
Despite these advantages, the development of CAR-NKs have faced several key challenges — in particular, manufacturing difficulties and limited scalability, their sensitivity to cryopreservation leading to a loss of viability and cytotoxicity, and a limited ability to efficiently introduce genetic modifications. Importantly, against solid tumors, the addition of a CAR to overcome KIR inhibition in an NK cell overrides their endogenous ability to target multiple receptors and results in a single antigen targeting CAR with the same limitation towards relapse due to tumor heterogeneity and ultimately antigen escape as a CAR-T.

The inherent and engineered limitations of these therapies, particularly in the solid tumor setting, creates substantial opportunity for improved and differentiated cell therapies for cancer.

# Why Gamma-Delta T Cells?

Gamma-delta T cells are a unique subset of immune cells that sit at the nexus of the innate and adaptive immune systems and possess properties of both, performing diverse immune functions including protection against tumors. This combination of features conveys functional abilities that make them ideally suited for use in cell therapy against cancer. They typically account for up to 10% of T cells but can undergo rapid activation and expansion in response to diseased or damaged tissue. Gammadelta T cells are multifunctional with a complex receptor repertoire including the semi-invariant T cell receptor, or TCR, which allows them to distinguish between healthy and diseased or stressed tissue. This distinct mode of antigen recognition is a critical feature that distinguishes them from not only alphabeta T cells but also B cells and NK cells. Gamma-delta T cells can kill effectively, both by direct cellular killing as well as the recruitment of additional immune cell types to induce killing. Importantly, gammadelta T cells can kill in situations where other immune cells cannot, such as a downregulation of MHC expression or matched KIR.

Gamma-delta T cells have been referred to as "nature's CAR-T cells" because their complex antigen recognition allows them to naturally and effectively target and eliminate diseased tissues, such as tumor tissue. As shown in Figure 3 below, their diverse receptor repertoire may enable them to recognize and target the array of multiple antigens expressed by solid tumors, which has been a significant challenge to existing single-antigen targeting CAR technologies using NK and alpha-beta T cells.



 $\alpha\beta$ = alpha-beta; γδ = gamma-delta

Figure 3. "Nature's CAR-T Cell"

Gamma-delta T cells also have the inherent ability to recognize a broad array of cellular stress signals, leading to both direct tumor cell killing as well as activation of a multifaceted immune response. Gamma-delta T cells have been observed to directly recognize and respond to a variety of MHC-like stress-induced self-antigens expressed by malignant cells without previously having the antigen presented, similar to NK cells. This recognition of stress antigens is achieved through a combination of gamma-delta TCRs, natural killer receptors, or NKRs, such as NKG2D, and toll-like receptors, or TLRs. This diversity of receptors is central to gamma-delta T cells' ability to identify healthy versus diseased tissue and may also contribute to their ability to effectively target cells, such as tumor cells with high variability and/or heterogeneity, thereby reducing antigen escape.

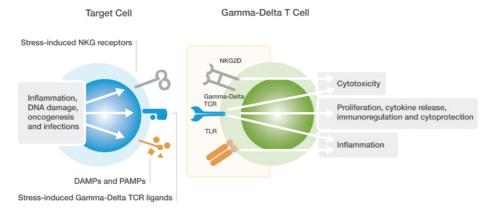


Figure 4. Innate Immune Cell Receptors of Gamma-Delta T Cells

The following highlights key potential advantages of gamma-delta T cells in comparison to other cell therapies for cancer:

 Differentiate between healthy and cancer cells. By using a combination of signaling receptors, including gamma-delta TCR, NKG2D and TLR, among others, gamma-delta T cells can safely distinguish between safe and dangerous tissues, such as cancerous tissues, within the body.

- Attack the heterogeneity of solid tumor cancers. The tumor contains cells that express a
  variety of antigen targets at different levels of expression. The complex and polyclonal binding
  abilities of gamma-delta TCR and NKG2D receptor allow them to broadly target diseased
  tissue and cover the heterogeneity of the tumor.
- Recruit and activate additional immune effector cells. Gamma-delta T cells broaden the immune response both through secretion of effector cytokines and chemokines that recruit and stimulate immune cells at the tumor. Gamma-delta T cells can elicit dendritic cell, or DC maturation by conveying danger associated molecular patterns, or DAMPs, and pathogen associated molecular patterns, or PAMPs to such cells. Certain subtypes of gamma-delta T cells also function directly as professional antigen presenting cells, or APCs, that activate and instruct alpha-beta T cells, similar to other innate immune cells like DCs, in order to elicit a potent and selective adaptive immune response
- Safety advantages over other cell therapies. Gamma-delta T cells do not recognize allogeneic MHC restricted antigens and thereby can be obtained from a partially matched or even unmatched donor, which may eventually allow these cells to be used 'off-the-shelf'. Gamma-delta T cells also do not secrete IL-6, a significant driver of cytokine release syndrome, or CRS, which has been a fatal complication in CAR-T in acute leukemias.

#### How Gamma-Delta T Cells Kill

The biology of gamma-delta T cells is complex, with multiple mechanistic approaches to effectively recognize, target and directly kill tumor cells, as shown in Figure 5 below. This allows them to drive towards deeper immune responses through immune cell recruitment and activation, cytokine release and antigen presentation:

- *Induction of cellular apoptosis*. Fas ligand, or CD95L, and tumor necrosis factor-related apoptosis-inducing ligand, or TRAIL, are both well-known triggers of cell death. These proteins are expressed on gamma-delta T cells, which allows them to engage the death receptors on target cells, leading to the direct destruction of cancer cells.
- Secretion of cell-killing enzymes and proteins. Gamma-delta T cells secrete granzymes, cell killing enzymes, that are typical of killer cells and cytotoxic T cells, and perforin, a protein that opens a hole in the target cell, allowing for the entry of granzymes. This can lead to apoptosis, or programmed cell death, in the same manner as NK cells.
- Antibody-dependent cellular cytotoxicity. Antibody-dependent cellular cytotoxicity, or ADCC, is cell-mediated cell killing, an efficient killing mechanism employed by the immune system. ADCC is triggered by the recognition of tumor-targeting antibodies through the CD16 expressed on gamma-delta T cells, similar to NK cells. This mechanism could allow the combination of gamma-delta T cell therapy with FDA-approved monoclonal antibody therapeutics, such as Rituxan, designed to enhance the effect of the antibody.

# Activated Gamma-Delta T Cell Tumor Cell Death Receptor 4/5 Fas-L Fas ADCC CD16 ADCC

Figure 5. Multiple Cell-Killing Mechanisms of Activated Gamma-Delta T Cells

#### Opportunities for Gamma-Delta T Cells in Cancer

The therapeutic potential of gamma-delta T cells is supported by observations over the last 20 years demonstrating a significant clinical correlation between naturally occurring high levels of gamma-delta T cells and better survival outcomes in both hematologic and solid tumor cancers. Our founder and Chief Scientific Officer, Dr. Lamb, was the first person to report an association between levels of gamma-delta T cells and improved survival in leukemia patients undergoing allogeneic HSCT. His work, published in *J. Hematotherapy* in 1996, as depicted in Figure 6 below, and expanded on in a publication in *Cytotherapy* in 1999, found that the disease-free survival rate of HSCT patients who received T-cell depleted, or TCD, cells from a partially matched donor increased in those with high levels of gamma-delta T cells. These findings have been supported by the reported studies of other scientists. In 2007, Dr. Lamb and his collaborators found that the association between post-transplant gamma-delta T cells and survival extended to at least seven years, and that 71% of patients with high levels of gamma-delta T cells survived up to seven years compared to 20% of patients with low levels of gamma-delta T cells.

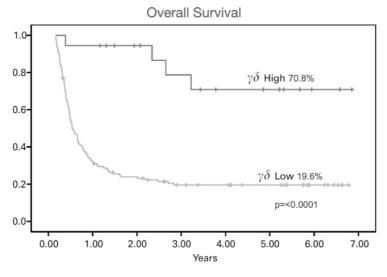


Figure 6. Correlation of Naturally Occurring Gamma-Delta T cells and Long-Term Survival in Leukemia

A Stanford University analysis of tumor-infiltrating immune cells in approximately 18,000 human tumor samples found that among all the subtypes of immune cells analyzed, the presence of gammadelta T cells as tumor infiltrating lymphocytes, or TILs, was the most highly correlated with overall survival, as shown in Figure 7 below. Patients with solid tumors containing gamma-delta T cells were significantly more likely to improve and potentially survive than those without gamma-delta T cells present.

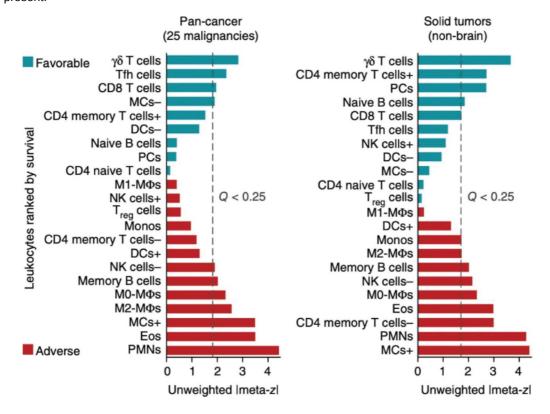


Figure 7. Prognostic Association of Tumor Infiltrating Lymphocytes and Survival Outcomes

While gamma-delta T cells have demonstrated clinical association with specific tumor responses, there have been significant hurdles to developing them as cell therapies, particularly for solid tumors. Gamma-delta T cells comprise less than 10% of all lymphocytes found in the body, and as such have been challenging to manufacture in quantities sufficient to meet the significant doses generally required for efficacious cell therapy. In addition, as cancer progresses, the levels of gamma-delta T cells are further reduced, making it challenging to engage them *in vivo*. Finally, gamma-delta T cells are critical in identifying stress antigens on diseased tissue, such as tumor cells. These signals can be dramatically upregulated by chemotherapy, which stresses both the chemotherapy-sensitive and chemotherapy-resistant tumor cells, making them readily identifiable by gamma-delta T-cells. Chemotherapy can both kill the immuno-suppressive cells and induce tumor cell death to break up or "de-bulk" the tumor. This opens up the TME to effector cells, such as gamma-delta T cells. However, chemotherapy also depletes and damages immune cells, including gamma-delta T cells, limiting their ability to seek and kill tumor cells.

# Preclinical Studies Have Demonstrated a Role for Gamma-Delta T Cells in Cancer

The clinical observations described above are supported by a broad base of preclinical research. Gamma-delta T cells have been shown to play a significant role in tumor immunosurveillance. Preclinical studies have demonstrated that genetically engineered mice deficient in gamma-delta T cells were highly susceptible to carcinogen-induced skin cancers. Similarly, prostate cancer growth was accelerated in mice deficient for gamma-delta T cells compared to fully immunocompetent mice. Gamma-delta T cells have been detected in a variety of human tumor types, including GBM, neuroblastoma and lung

cancer, demonstrating that gamma-delta T cells infiltrated such solid tumors and thus may have an important correlation with anti-cancer activity. Prior data, including our own unpublished studies, have indicated that levels of gamma-delta T cells were diminished as cancer progresses and were depleted in end-stage disease.

#### **Our DeltEx Platform**

We develop *ex vivo*-expanded activated gamma-delta T cells 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 is designed to overcome many of the challenges associated with expansion, genetic engineering and scalable manufacturing of gamma-delta T cells. This allows us to expand the cells *ex vivo* to administer a potentially therapeutic dose to patients, harnessing the unique properties of gamma-delta T cells, including their ability to broadly recognize cellular stress signals on tumor cells. DeltEx has enabled our deep pipeline of innovative allogeneic, autologous and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes. Key elements of our platform include:

- Expertise in ex vivo-expanded activated gamma-delta T cells. Gamma-delta T cells, while critical to immune function and disease response, account for a small percentage of our immune cells. Our approach leverages our scientific expertise in gamma-delta T cell biology, encompassing the work of our scientific founder Dr. Lamb, to perform precise cell-type specific ex vivo expansion. This enables us to take peripheral blood from the patient and selectively expand the low numbers of gamma-delta T cells in order to generate a sufficient dose for treatment of solid tumors. Our expertise allows us to expand the desired subtypes of the gamma-delta T cell population, perform specific genetic modifications, and complete a quality review of these cells before returning precisely controlled doses to patients. This precision, control and quality provides significant advantages over in vivo expansion, which may not be cell-type specific, and we believe it uniquely enables us to potentially develop a therapeutic candidate at scale.
- Intelligent gamma-delta T cell genetic engineering. We have developed proprietary methods of engineering gamma-delta T cells that are designed to take advantage of their inherent biology. Our engineering is designed to increase their ability to survive chemotherapy or to identify cancer cells while maintaining their natural ability to broadly recognize, engage and kill these cells. This enables the cells to be delivered concurrently with chemotherapies that activate the DNA damage response, or DDR pathway to generate an immune signal that should be expressed on all cells throughout the tumor and recognized by gamma-delta T cells. This intelligent engineering is broadly applicable across multiple solid tumor indications. Our approaches have overcome the historical problems in genetically modifying gamma-delta T cells, and we are currently the first company to advance a Phase 1 clinical trial using genetically modified gamma-delta T cells.
- Next-generation gamma-delta T cell manufacturing. We have devoted significant time and resources to process development and manufacturing to improve the quality and reproducibility of our processes. Through our intellectual property and scientific know-how, we have designed and implemented a manufacturing process, including proprietary programs, which is designed to be reliable and scalable. We have automated our manufacturing processes, which are currently operating at clinical scale, in a system designed to minimize touchpoints and potential contamination and increase throughput. Our cell-type specific manufacturing platform is designed to support rapid development of our DeltEx product candidates through clinical trials and the regulatory approval process. We are using an automated, fully enclosed system for cell manufacturing, as shown in Figure 8 below, that is designed to be applicable across all our product candidates. Our manufacturing allows us to scale, while maintaining quality controls, which would be challenging with a manual lab-scale process. We have optimized transduction and cell expansion in a process we believe can be rapidly scaled for commercial supply in a controlled environment at a reasonable cost, if any of our product candidates are successfully developed and approved. We have also demonstrated successful cryopreservation

and delivery of our thawed product candidates to patients in our clinical trials, while maintaining cell viability and functionality.

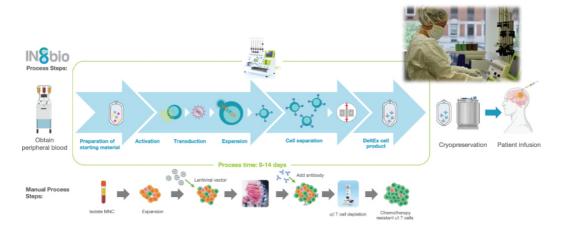


Figure 8. Reproducible & Scalable Manufacturing Process

#### Scientific Basis for Harnessing Vd2+ Gamma-Delta T Cells

There are several diverse subsets of gamma-delta T cells. The most predominant circulating subsets are the Vdelta2 positive, or Vd2+, and the Vdelta1 positive, or Vd1+. These cell types have specific features that impact their therapeutic potential across different indications. Vd2+ cells comprise approximately 2 to 10% of the circulating cell population. The Vd1+ cells are a minor (<2%) circulating subset, but abundant in specific tissues, such as the intestines and the skin. While both subsets express NKG2D receptors that recognize stress ligands, only the Vd2+ subset can function as a professional antigen presenting cell, which can process and present antigens, recruit and activate additional immune cell types. While there may be a potential utility for the Vd1+ subset for some cancers, we are currently focused on developing therapeutic candidates using Vd2+ cells, which we believe have certain advantages over the Vd1+ subset. The use of Vd1+ cells as a therapeutic has two potential challenges. First, while Vd1+ cells have shown greater persistence, research indicates that there is tissue specific tropism, or a signal, which functions to drive cells into specific tissues and maintain them there, potentially making it difficult to traffic to tumors outside these tissues. As an example, a third-party 2019 study demonstrated that skin-derived Vd1+ cells express the receptors that prevent them from migrating out from the dermis. The second challenge is the potential for Th1 effector Vd1+ cells to undergo reprogramming to a tumor promoting Th17, or IL-17 secreting, subtype. While current ex vivo expansion methods for Vd1+ cells have not resulted in pro-tumorigenic Th17-type responses to date, the potential for reprogramming of therapeutic Vd1+ cells remains a possibility. In contrast, Vd2+ cells are not known to produce Th17 or pro-tumoral subtypes.

We are currently focused on advancing programs utilizing Vd2+ cells, using our cell-type specific expansion protocol, which produces cytotoxic Th1 gamma-delta T cells at scale. We have developed our DeltEx platform to enable us to expand, activate and genetically modify Vd2+ cells at scale, producing cells which are viable, functional and can be cryopreserved while maintaining their cytotoxicity.

# Our Lead Gamma-Delta T Cell Product Candidates

#### INB-200 for the Treatment of Solid Tumors

INB-200 is our novel genetically modified autologous DeltEx product candidate that we are developing for the treatment of solid tumors. We engineered INB-200 to be used as an adjuvant to the current standard-of-care treatment by engineering it to be resistant to certain types of alkylating chemotherapies. Alkylating chemotherapies function by creating DNA damage and strand breaks that lead to cell suicide or apoptosis. The protein O-6-Methylguanine-DNA Methyltransferase, or MGMT is a primary DNA repair protein capable of repairing damage to DNA caused by certain chemotherapies that prevents cell death. Through the introduction of a gene encoding MGMT into gamma-delta T cells,

these genetically modified DeltEx DRI cells are designed to survive concurrent dosing with chemotherapy and remain functional. In preclinical studies in patient derived xenografts, INB-200 demonstrated antitumor activity, including long-term survival and eradication of the tumor as evidenced by histopathology. We are initially developing INB-200 to treat newly diagnosed patients with GBM during the maintenance phase following resection and initial radiotherapy and chemotherapy. We are conducting an investigator-initiated Phase 1 repeat dose escalation clinical trial in patients with newly diagnosed GBM, which has been initiated by L. Burt Nabors, M.D. at the O'Neal Comprehensive Cancer Center at UAB. We expect to report the initial results from the second cohort in this Phase 1 trial by the end of 2021.

# Glioblastoma (GBM) Overview

GBM is a particularly aggressive form of brain cancer, in which tumor cells invade the surrounding tissue, rendering surgical resection and chemotherapy less effective. The incidence of GBM in the United States is estimated to be approximately three in 100,000 individuals, with more than 10,500 new cases estimated in 2020. Surgical resection followed by radiation and TMZ has been the current standard-of-care since 2005, but it is only able to control tumor growth in approximately 30% of patients. Based on current standard-of-care, tumor recurrence typically occurs within one year after initial diagnosis and treatment. A third-party trial published in 2017 indicated that older newly diagnosed GBM patients with unmethylated MGMT treated with radiation therapy and TMZ had median progression free survival of only 4.8 months (95% CI (4.3-5.6)).

#### Our Solution — INB-200 for the Treatment of Newly Diagnosed GBM

We engineered INB-200 using a lentiviral vector to introduce the gene for MGMT, which is the primary protein capable of repairing DNA damage caused by alkylating chemotherapeutic drugs, such as TMZ. Tumor cells that over-express MGMT are resistant to TMZ and the current standard-of-care in GBM. By introducing MGMT into our DeltEx gamma-delta T cells, these genetically modified cells are designed to avoid TMZ-induced cell death. There is also considerable preclinical support for the use of gamma-delta T cells for the treatment of GBM.

There is a significant unmet need as most patients with GBM die within 15 months of diagnosis and the five-year survival rate is approximately 5%. Over 80% of treated GBM patients recur within 2cm of the original resection site, suggesting that recurrence is not due to metastases, but due to microscopic residual tumor that was not surgically resectable and is resistant to radiotherapy and chemotherapy. We believe that to have a clinically meaningful impact to patient outcomes, we must be able to target three categories of cells within the tumor: (i) cells sensitive to radiotherapy and chemotherapy, (ii) cells resistant to chemotherapy and (iii) cancer stem-like cells that are able to avoid immune detection. By combining our INB-200 therapeutic candidate concurrently with alkylating chemotherapies, our approach can promote the upregulation of stress ligands across all three of these categories, making the GBM cells identifiable by our DeltEx DRI cells. We believe this may be able to drive to deeper antitumor immune responses that could lead to prolonged progression free survival and increased overall survival. If our INB-200 clinical trials demonstrate antitumor activity at a level that the FDA deems to be clinically meaningful, we may be able to pursue accelerated approval pathways.

We believe newly diagnosed GBM is well suited initial indication to assess the potential of INB-200 to drive clinical antitumor activity. A recent third-party paper analyzing the impact of pre-conditioning on the TME to enhance solid tumor CAR-T cell therapy indicated that CAR-Ts have been hampered by immune suppression, escape of tumor antigens from single antigen targeting CARs, and T cell trafficking as adoptively transferred cells are trapped in first-pass tissues such as the lung and liver. Our DeltEx DRI approach in newly diagnosed GBM was specifically designed to overcome these challenges, among others. The administration of INB-200, through a cranial catheter, directly to the tumor site may increase the effector:target ratio, or E:T, and limit the ability of the introduced cells to migrate out of the brain, which has been shown to improve the antitumor activity of cell therapies over intravenous delivery. In the past, other novel modalities, such as treatment with adeno-associated virus or siRNAs, demonstrated early clinical response by also targeting locally deliverable organ systems such as the eye or liver.

# INB-200 — Investigator-Initiated Phase 1 Clinical Trial

We are conducting an investigator-initiated Phase 1 repeat dose escalation trial of INB-200 at the O'Neil Comprehensive Cancer Center. We expect this trial to enroll up to 12 patients with newly

diagnosed GBM who have completed a standard TMZ chemotherapy and radiotherapy treatment and are eligible to initiate maintenance therapy with TMZ.

The primary endpoint of this trial is to assess the safety and tolerability, in a small number of individuals, of expanded and activated autologous MGMT genetically modified gamma-delta T cell infusion. Safety will initially be assessed at single and multiple infusions at a dose level of 1x10<sup>7</sup> DeltEx DRI gamma-delta T cells through a fenestrated intracranial catheter. Secondary endpoints include overall survival, time to progression and response. We will also assess biologic activity including cytokine and cellular analysis, both peripherally and from the cerebral spinal fluid, or CSF, if available. This clinical strategy takes advantage of gamma-delta T cell cytotoxicity against GBM since it is administered during chemotherapy, when a tumor is experiencing maximum stress and increased immunogenicity.

Eligible patients will receive standard-of-care therapy, which includes surgical resection of the GBM tumor, post-surgical TMZ and radiation therapy, followed by maintenance TMZ in combination with INB-200, as shown in Figure 9 below. During resection, an intracranial catheter is placed for injection of the INB-200 product. Blood cells for genetic modification are taken from the patient by leukapheresis several weeks following resection, after the patient's immune system has been allowed to recover. Gamma-delta T cells are then isolated, genetically modified and expanded into the INB-200 product candidate, and then cryopreserved. No more than six weeks post-surgery, patients are treated with daily radiation and TMZ for six weeks followed by a four-week break. Following the four-week period, corticosteroid use is usually tapered, and the patient begins a maintenance phase of TMZ for the first five days of each 28-day cycle for up to six cycles.

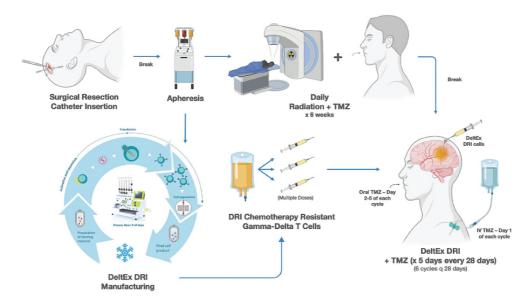


Figure 9. INB-200 Administration Protocol

The decision to combine INB-200 in the newly diagnosed GBM setting as an adjuvant to standard-of-care therapy was driven by biology, data and the desire to overcome challenges as outlined above. In this trial, we seek to attack any residual tumor cells when they are most vulnerable and with immune cells that are as healthy as possible. By combining INB-200 with surgical resection, chemotherapy and radiotherapy, we hope to eliminate the bulk of the tumor and target the residual tumor with a different biological mechanism that could potentially drive both deeper antitumor immune responses and improved safety due to the lower tumor burden.

Patients are dosed with adjuvant INB-200 via intracranial catheter injection, as shown in Figure 9 above, within four hours of receiving intravenous dosing with TMZ on day one of the maintenance cycle. Oral dosing of TMZ will continue for the four subsequent days during each 28-day treatment cycle, as

shown in Figure 10 below. Depending on which dose cohort they are enrolled in, patients will be administered either one, three or potentially up to six injections of INB-200.

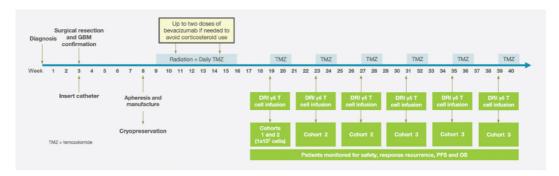
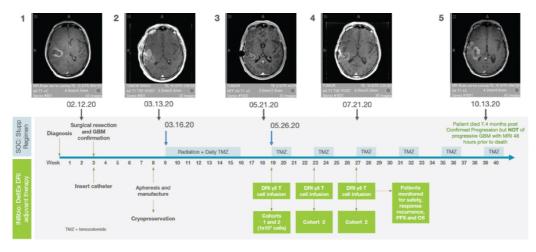


Figure 10. Treatment and Manufacturing Timeline of the INB-200 Phase 1 Trial

To date, nine patients with newly diagnosed GBM have been enrolled in this trial and four patients comprising the complete first cohort and one in the repeat dose cohort have been dosed with INB-200, our DeltEx DRI product. Three patients in the multi-dose cohort, or dose level 2, have been enrolled and recently initiated their treatment protocols. The patients in cohort 1 each received a single dose of INB-200, following a minimum of 30 days for safety observation. As of June 30, 2021, four patients have received a single dose of INB-200. No infusion reactions, cytokine release syndrome, neurotoxicity, or other dose limiting toxicities or serious treatment-emergent adverse events were observed in the first cohort, allowing us to proceed to the next cohort. This second cohort will receive three doses of INB-200, 28 days apart. We have amended the protocol to add a third cohort where patients will receive up to six doses of INB-200, 28 days apart. Following treatment, all patients will be monitored for time to disease progression and for overall survival.

The first patient (001) had several poor prognostic factors, including age (older at 68 years old), male, MGMT unmethylated (non-responsive to TMZ), and IDH wild-type GBM. Figure 11 below depicts patient 001's treatment timeline. Following treatment with INB-200, MRI reports indicated no nodular masses or evidence of disease progression observed as indicated in representative image 4 below. At 8.3 months following tumor resection, patient 001 showed evidence of local recurrence on routine MRI examination but remained clinically asymptomatic and off corticosteroids (image 5). Tumor re-resection confirmed progression and histologic examination of the resected tumor revealed large areas of necrosis and a high concentration of TILs, including CD3+, CD4+ and CD8+ T cells and a few CD20+ B cells.



\*Results from one patient are not indicative of future results, including the outcome of this trial.

Figure 11. Patient 001

This patient died at 477 days following complications related to the treatment of a pancreatic cyst unrelated to the GBM. An MRI two days prior to death demonstrated that the tumor remained stable 7.4 months following progression. The patient's overall survival was 15.6 months post initial surgical resection and enrollment into this Phase 1 trial, which was beyond his expected median overall survival of 10 months based on his greater age and MGMT status.

A second patient (002) is a 48 year-old male with MGMT unmethylated, IDH wild-type GBM, who experienced non-expansion of gamma-delta T cells after leukapheresis, and therefore, was not given INB-200, but consented to continue to be monitored for disease progression. This expansion failure was likely due to the highly globally immunosuppressive nature of his tumor. This patient demonstrated enhancement on MRI on day 182 and was subsequently confirmed to have progressed at day 231 or 7.6 months. We continued to monitor this patient for overall survival, and to collect peripheral blood samples to determine the patient's immunologic status as a comparator to patients who received INB-200. Patient 002 died due to progression of disease at day 354 or 11.6 months.

The third patient (003) is a 74 year-old female with MGMT methylated (sensitive to TMZ), IDH wild-type GBM. Following surgical resection and prior to initiation of treatment with chemoradiation, this patient experienced a serious adverse event of dehydration associated with a urinary tract infection and fever. In addition, grade 2 cranial incision site drainage and edema further complicated this patient's course. Both events were determined not to be INB-200 infusion related since the events occurred prior to the INB-200 injection. The events resolved and the patient continued on protocol. Following chemoradiation, she was treated with INB-200 in November 2020, did not experience any infusion related treatment-emergent adverse events, and was determined to have stable disease following cycle 2 of maintenance TMZ. This patient experienced a grade 3 thrombocytopenia, likely related to her TMZ standard of care therapy, but recovered with spontaneous platelet recovery without additional intervention or platelet infusions. As of June 30, 2021, this patient remained clinically stable beyond her expected median progression free survival of 7.9 months with no disease progression, remains on study at 354 days or approximately 11 months, and has not required the use of steroids.

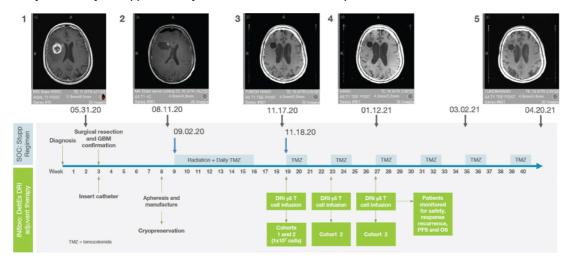
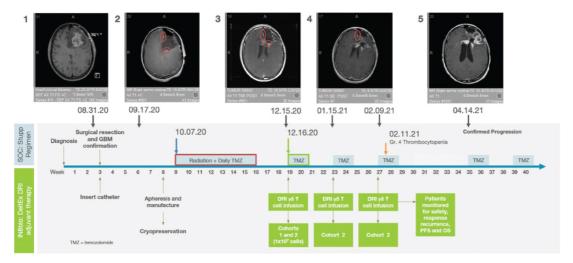


Figure 12. Patient 003

The fourth patient (004) is a 21 year-old female also with multiple poor prognostic factors including MGMT unmethylated, IDH wild-type GBM, who received a left frontal lobe surgical resection in September 2020. Post resection, as shown in the MRI (image 2 in Figure 13 below), there was residual tumor present in the medial and inferior margins of the resection cavity. Prior to receiving treatment with INB-200, in December 2020, MRI scans were performed which noted an interval increase in the residual tumor and appreciation in abnormal enhancement (image 3 below) relative to scans made post-resection in September 2020 (image 2). Importantly, this increase was observed following six weeks of daily radiation and TMZ treatment. The patient was then treated with a single dose of INB-200. One month later in January 2021, during a follow-up scan after treatment with INB-200, a slight interval

improvement was observed in the nodular hyperintense changes and on administration of contrast, a reduction in enhancement was observed. As shown in image 4 below, residual disease remained with no new or satellite areas noted, but there was a reduction in the size of the nodular areas and in vasogenic edema. In February 2021 a follow-up MRI demonstrated stable-disease with no new areas of abnormal enhancement and no tumor progression. Following this MRI, during cycle 3 of TMZ treatment, patient 004 experienced a grade 4 thrombocytopenia in February 2021 that is likely associated with her treatment with TMZ on the Stupp regimen. Grade 3/4 thrombocytopenia occurs in approximately 25% of newly diagnosed GBM patients being treated with the Stupp regimen. The patient's platelets recovered spontaneously with no intervention and no transfusions following a delay of additional treatment with TMZ. A follow up MRI after the delayed treatment of cycle 4 of TMZ demonstrated aggressive progressive disease at 224 days or 7.4 months. MRI demonstrated increased hyperintensity, new enhancement along the resection cavity and into the ventricles and additional enhancement demonstrating contralateral extension. The patient initiated treatment with radiation, TMZ and bevacizumab, and died due to progressive disease at 293 days or 9.6 months.



\*Results from one patient are not indicative of future results, including the outcome of this trial.

Figure 13. Patient 004

In 2020, we enrolled two additional patients (005 and 006) and initiated their treatment protocols, but both subsequently withdrew from the trial for personal reasons. Patient 005 had their surgical resection with catheter insertion, had successfully completed leukapheresis and DRI manufacturing and had begun the standard-of-care radiation and concurrent chemotherapy. During this phase of standard-of-care therapy, patient 005 experienced seizures which led to hospitalization and did not have any local family support due to COVID-19. In late December 2020, patient 005 made the personal decision to discontinue treatment and move on to hospice care. Patient 005 did not receive an infusion of INB-200 and died on day 142 or 4.7 months due to progression of disease. Treatment for patient 006 included surgical resection with catheter insertion. Prior to apheresis, patient 006 withdrew consent for personal reasons and chose to discontinue participation in the trial but is being monitored for overall survival.

Three patients in the first multidose cohort have been enrolled. Patient 007 is a 74 year-old male with MGMT unmethylated and IDH-wild-type GBM, who has completed treatment with radiation and chemotherapy and initiated the planned first of three doses of INB-200 in June 2021. Patient 008 is a 76 year-old male with MGMT methylated and IDH wild-type GBM, who had been surgically resected, apheresed and during manufacturing their T cells failed to adequately expand. We will continue to monitor this patient for tumor progression and overall survival. Patient 009 is a 32 year-old male with MGMT unmethylated and IDH mutant GBM, who has been surgically resected, had a successful manufacturing, and awaits initiation of radiation and chemotherapy. We are actively recruiting additional patients into this trial.

As of June 30, 2021, we have treated the first three patients with a single dose of INB-200 and have not observed any injection reactions, severe adverse events, or adverse events deemed related to the injection of INB-200, including cytokine release syndrome or neurotoxicity. One patient experienced a subdural hygroma with no neurological symptoms deemed related to the surgical procedure prior to the INB-200 treatment. Reported grade 3/4 adverse events include dehydration, seizure related to disease, thrombocytopenia and urinary tract infection. The other adverse events reported to date were grade 1/2 anorexia, anosmia, edema, fatigue, fever, headache, leukopenia, nausea and vomiting, related to radiation and TMZ chemotherapy. The data from this first dose level were reviewed by the data safety monitoring board (DSMB) in February 2021. The DSMB determined it was safe to proceed and progress to the repeat dose cohort (or dose level 2).

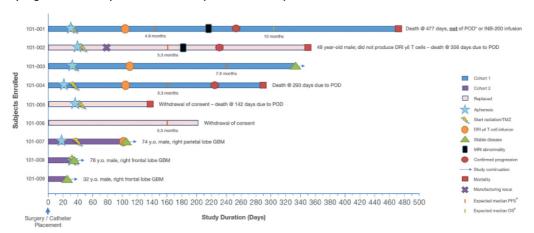


Figure 14. Summary of Patients Enrolled in INB-200 Phase 1 Trial

Figure 14 depicts subject disposition. To date, two patients dosed with INB-200 injection remain alive. Patient 001 lived to 15.6 months and died due to complications related to the treatment of a pancreatic cyst and not due to progression of GBM. Patients 001 and 004 had progressive disease, which occurred beyond their expected median time to progression. Patient 003 remains on study with stable disease at 11 months post resection. Of the untreated patients enrolled, two of three have died due to progression of disease.

We expect to report initial results from the second cohort in this Phase 1 trial by the end of 2021. In the second quarter of 2020, we amended the protocol to add a third cohort of patients that will receive up to six doses of INB-200, with data expected in 2022.

# ASCO 2021 Annual Meeting Presentation

At the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting, we presented additional immunologic and correlative analysis data from the three patients in the first cohort who received INB-200 (Figure 15). In the treated patients, circulating T cells were suppressed in two of three subjects at diagnosis due to the globally immunosuppressive GBM. The third patient, 004, a 21 year-old female, initially showed a higher than normal T cell count which decreased into the normal range following resection. GBM resection temporarily reverses systemic immunosuppression causing T cell counts to normalize, however, the following 6-week chemotherapy regimen then followed by lymphodepleting effects of maintenance-phase TMZ, generally keep T and NK cell counts at low/normal or below normal range. This continuous suppression of peripheral lymphocyte effector cells demonstrates the advantage of direct placement of TMZ-resistant gamma-delta T-cells in the resection cavity. Infusion of a single 1x10<sup>7</sup> DeltEx DRI gamma-delta T cells dose directly into the brain revealed measurable changes in circulating lymphocyte populations, specifically a transient increase in circulating gamma delta T cells in all three patients. We continue to study correlative immune activity by examining peripheral blood and local CSF cytokine activity as well as circulating tumor DNA, exosomes, proteins, and cell-free nucleic acids for the purpose of understanding disease state, response to therapy, and potential toxicities.

Figure 15. Immunologic and Correlative Analysis from Subject Peripheral Blood Samples

#### INB-200 — Preclinical Studies in GBM

Malignant high-grade GBM in both humans and mice express stress ligands that are known to activate NKG2D and are targets for gamma-delta T cell attack. In preclinical testing, gamma-delta T cells exhibited strong cytotoxic activity against several GBM cell lines and primary explant cultures. Normal human brain cells do not express these stress ligands and are not affected.

To assess the antitumor activity of exogenous gamma-delta T cells in GBM as an initial proof-of-concept, it was observed that *ex vivo*-expanded and activated human gamma-delta T cells prevented emergence of tumors in a U251 GBM model in immunocompromised mice, leading to increased overall survival.

In immunocompetent mice, we found that implantation of GL261 GBM cell line tumors led to a significant increase in levels of endogenous gamma-delta T cells, however these levels decreased over time coincident with tumor progression. Previous clinical studies in GBM and in extracranial malignancies have shown that this decrease is likely a result of T cell exhaustion due to their continuous stimulation by a large and highly aggressive tumor. Indeed, in this study we showed that the increased peripheral blood gamma-delta T cells seen in response to the tumor were already expressing the pre-apoptotic marker Annexin V. Exogenous administration of gamma-delta T cells into the brain immediately after tumor implantation increased overall survival in this model, however these results were not statistically significant.

# Improved Antitumor Activity in Combination with Chemotherapy

Based on several years of peer-reviewed and published preclinical work, as well as early human cancer trials, we believe that INB-200 can work in synergy with chemotherapy by causing changes in cancer cells that result in increased expression of activating ligands of gamma-delta T cell and NK cell function, such as NKG2D. In preclinical studies, treatment of TMZ-resistant GBM cells derived from the U87 human GBM cell line with TMZ led to transient increases in a broad panel of stress ligands recognized by the NKG2D receptor, as shown in Figure 16 below.

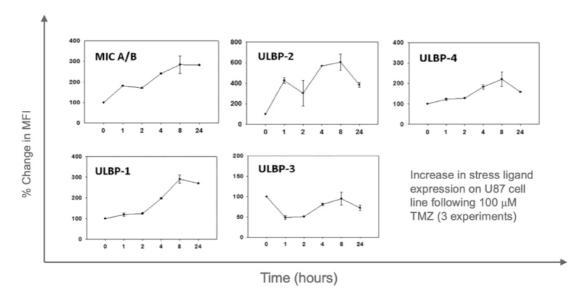


Figure 16. Increased NKG2D Ligand Expression Observed on TMZ-Resistant Tumor Cells Treated With TMZ

As shown in Figure 17 below, additional studies in glioma cells have demonstrated that NKG2D ligands are also expressed on cancer stem cells, considered as cells that express factors, such as Klf-4, Oct-4, Sox-2, Nanog and Musashi-1. Treatment with TMZ demonstrated that NKG2D ligand expression can also be upregulated several fold on GBM stem-like cells, as depicted in Figure 18 below. This increase in stress ligand expression, even in TMZ-resistant and stem-like cancer cells, has the potential to increase the vulnerability of tumor cells to gamma-delta T cell targeting during the period of pharmacokinetic activity of TMZ.

	MICA	MICB	ULBP1	ULBP2	ULBP3
Klf-4	$43\% \text{ (SD} \pm 29\%)$	$76\% \text{ (SD} \pm 31\%)$	$76\% \text{ (SD} \pm 30\%)$	$12\% \text{ (SD} \pm 16\%)$	48% (SD±33%)
Oct-4	$22\% \text{ (SD} \pm 27\%)$	$9\% \text{ (SD} \pm 14\%)$	$89\% \text{ (SD} \pm 34\%)$	$21\% \text{ (SD} \pm 30\%)$	$21\% \text{ (SD} \pm 22\%)$
Sox-2	$35\% \text{ (SD} \pm 30\%)$	$25\% \text{ (SD} \pm 23\%)$	$88\% \text{ (SD} \pm 21\%)$	$14\% \text{ (SD} \pm 19\%)$	$43\% \text{ (SD} \pm 35\%)$
Nanog	$33\% \text{ (SD} \pm 21\%)$	$27\% \text{ (SD} \pm 27\%)$	$71\% \text{ (SD} \pm 30\%)$	$15\% \text{ (SD} \pm 21\%)$	$38\% \text{ (SD} \pm 28\%)$
Musashi-1	$47\% \; (SD \pm 45\%)$	$20\% \text{ (SD} \pm 35\%)$	$57\% \text{ (SD} \pm 27\%)$	0%	100%

Figure 17. Cancer Stem-Like Cells Co-Express Stem-Cell Markers and NKG2D Ligands

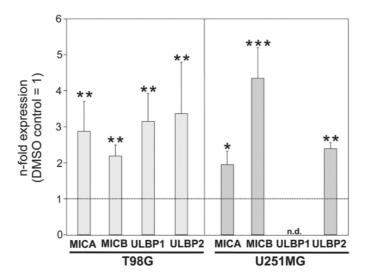


Figure 18. Increased NKG2D Ligand Expression in Glioma Stem Cells Treated with TMZ

There are two principal challenges to clinical application of TMZ treatment in conjunction with gamma-delta  $\mathsf{T}$  cells:

- TMZ is cytotoxic to immune cells, including gamma-delta T cells; and
- the increased expression of stress ligands is transient due to resistance mechanisms of the tumor.

Therefore, we believe the ideal gamma-delta T cell exposure would occur when TMZ is still pharmacokinetically active. We developed INB-200 in a way that could enable it to overcome both of these challenges by engineering the cells that make up INB-200 to be resistant to TMZ, an approach we refer to as DeltEx DRI. Treatment of GBM using TMZ increases the levels of NKG2D stress ligands expressed on the tumor cells leading to activation of INB-200. The introduction of the drug-resistant genes is designed to allow INB-200 to survive even when it is administered while TMZ is present even in concentrations above the clinical range. As depicted in in Figure 19 below, concurrent treatment with TMZ causes the direct killing of some tumor cells and immunosuppressive cells while activating gamma-delta T cells, which could lead to stimulating the antitumor activity of INB-200.

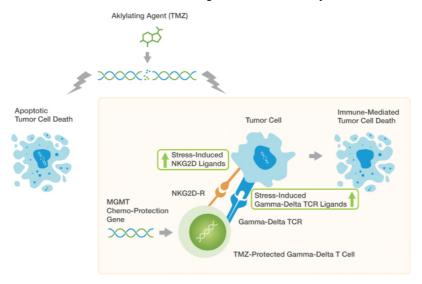


Figure 19. DeltEx DRI Mechanism of Action Targeting the DNA Damage Response (DDR)

We have developed a process to genetically modify gamma-delta T cells in order to add a gene that codes for MGMT production. MGMT, a primary DNA repair protein, prevents cell death by repairing the DNA double-stranded breaks caused by alkylating chemotherapy, such as TMZ. As shown in Figure 20 below, introduction of the gene encoding MGMT into gamma-delta T cells using a lentiviral vector decreased the sensitivity of these modified gamma-delta T cells to TMZ by approximately six-fold. A concentration of 63 micromolar, or  $\mu$ M, of TMZ inhibited the proliferation of unaltered gamma-delta T cells by 50%, whereas a concentration of 383  $\mu$ M of TMZ was required to have a similar effect in DeltEx DRI gamma-delta T cells. We observed that this gene modification did not alter other properties of these gamma-delta T cells, including their cytotoxicity against target cells.

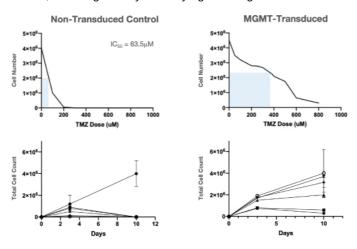


Figure 20. MGMT-Modified Gamma-Delta T Cells Demonstrate Protection Against Killing Effects of TMZ

In preclinical studies, we have observed that the *in vitro* anti-tumor effect of DeltEx DRI gammadelta T cells remained fully intact in therapeutic concentrations of TMZ. As depicted in Figure 21 below, the stepwise killing effect of increasing the E:T ratio of DeltEx DRI gamma-delta T cells on TMZ-resistant SNB-19 and U373 GBM cell line clones prepared for this study was amplified when the assay was conducted in therapeutic concentrations of TMZ. Both SNB-19 and U373 clones prepared for this study were resistant to TMZ and were not affected by the concentration of TMZ used in this assay. Our findings from this study suggest that this increased cytotoxicity is due to the upregulated expression of NKG2D stress-associated ligands on the tumor cells, which increased even in cells that were resistant to the direct cytotoxic effects of TMZ.

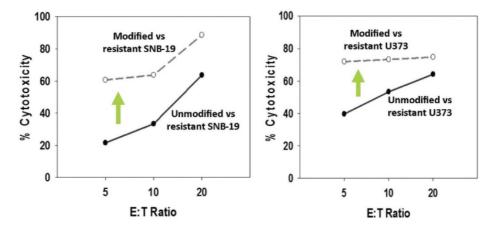


Figure 21. MGMT-Modified Gamma-Delta T Cells Demonstrated Increased Cytotoxicity Against GBM Cells in the Presence of TMZ

Driving to higher E:T ratios by using available therapies to debulk a solid tumor mass may be important *in vivo*. As depicted in Figure 22 below, a recent third-party paper in ovarian cancer patients demonstrated that the proportion of endogenous cytokine-producing gamma-delta T cells was inversely proportional to the amount of residual tumor following primary surgery. Patients with residual tumor burden of 0 cm or 0-2 cm produced significantly greater interferon-gamma, or IFN-g, and tumor necrosis factor-alpha, or TNF-a, than those tumors that had greater than 2 cm of residual tumor post-surgery.

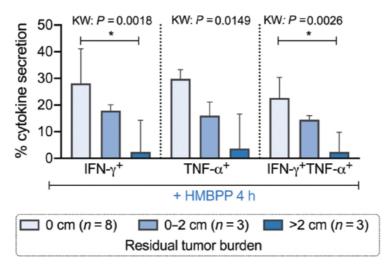


Figure 22. Gamma-Delta T Cell Cytokine Production is Inversely Related to Residual Tumor Burden in Ovarian Cancer

In preclinical studies of INB-200 in GBM patient-derived xenograft models, we observed that the combined dosing of TMZ and treatment with our DeltEx DRI gamma-delta T cells led to a statistically significant (p-value ≤ 0.05) increase in overall survival in primary GBM xenograft tumors, as compared to mice treated separately with either chemotherapy or gamma-delta T cells. Unmodified gamma-delta cells showed no survival benefit. Subsequent histopathological analysis demonstrated no visible residual tumors in INB-200-treated animals at 150 days, as shown in Figure 24 below. This is important, since xenograft models convey the heterogeneity of a human-derived tumor and not the monotonous population of a cell line used in syngenic models. Separately, we also examined the potential for sequencing chemotherapy and cell therapy, separating gamma-delta T cells from TMZ therapy by 24 hours (condition 1) and outside the effective concentration of TMZ. As shown in Figure 23 below, we observed that in TMZ-sensitive tumors treated with the sequenced regimen, delivery of the DeltEx DRI gamma-delta T cells led to modest improvement in median overall survival of 75 days compared to 60 days with TMZ alone but with no overall survival benefit over TMZ. Conversely, as discussed above, the combined and concomitant delivery of TMZ and DeltEx DRI gamma-delta T cell regimen (condition 2) resulted in 80% of mice surviving beyond 150 days. These results are consistent with our observations in cell lines, in which we observed that treatment with TMZ led to transient increase in the levels of NKG2D stress ligands. We believe the increased expression of these stress ligands, in turn, led to increased cytotoxic activity of the DeltEx DRI gamma-delta T cells. In preclinical studies, we observed that, even in TMZ-resistant tumors, administration of MGMT-modified gamma-delta T cells led to an increase in median and overall survival while sequencing TMZ and gamma-delta T cells showed no benefit.

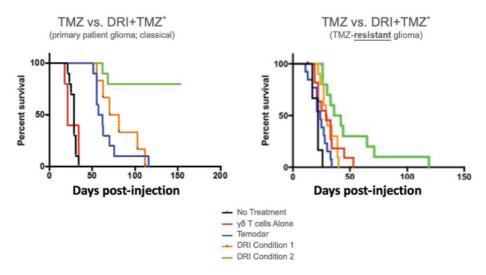
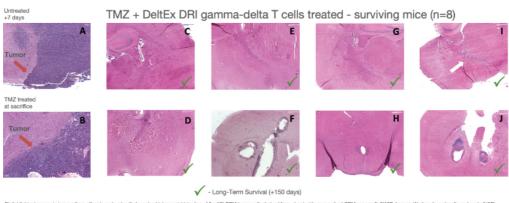


Figure 23. Improved Survival Observed in Both TMZ-Sensitive and TMZ-Resistant GBM Models



Digital light microscopic images from attrymor nucle mice that received intracranal injection of 5 x 10° GBM tumor cells derived from classical human patient GBM xemograft X712P, Images (A) show hematopyin and existing for tumor growth (dark purple in-noted by red arrow) from unbreated mice at +1 d says following sterelocation; tumor placement in the left causties neuties (dip; (B)) was obtained at eutharsais following faster location; tumor placement in the left causties neuties (dip; (B)) was obtained at eutharsais following faster location; to make a few formations of the left causties neuties (dip; (B)) was obtained at eutharsais following faster location; the left causties neuties (dip; (B)) was obtained at eutharsais following fast in the line of 
Figure 24. Histopathology Demonstrates No Residual GBM in Mice

These preclinical results are supported by observations of gamma-delta T cells in human cancer patients. As shown in Figure 25 below, in 2011, a group in Japan published results of an early clinical trial testing the adoptive transfer of *ex vivo*-expanded autologous gamma-delta T cells for the treatment of advanced solid tumors in the British Journal of Cancer. The paper discusses the need to evaluate combinations of gamma-delta T cell therapies with other therapies and how to appropriately time administration of such combination therapies to generate synergy and avoid damage to gamma-delta T cells. However, while no dose limiting toxicity was observed, most patients progressed, with progressive disease (n=12) or stable disease (n=3) being the predominant tumor responses reported. Three patients who were receiving other therapies and were progressing or considered unlikely to respond to standard therapy received gamma-delta T cells in parallel. All three patients demonstrated tumor responses with two partial remissions and one complete remission.

						% 70 T IN CD3+			Ex vivo expanded 70 1					
Patient		Primary cancer	Metastasis	Previous therapy	Previous Zol. treatment	Before expansion	After ex vivo expansion			Max. dose/ treatment (×10 <sup>9</sup> cells)	Total dose (× 10 <sup>9</sup> cells)		Clinical response	Comment
Group A (C		escalation/Zol. treatn	nent)											
Al	58/F	Melanoma	Lung	_	Yes	0.4 (2.0)	8.9 (2.8)	28 (13)	8	0.04	0.1	Yes	PD	
A2	59/M	Melanoma	Lung	_	Yes	2.4 (3.0)	23.5 (4.0)	8 (2)	8	0.2	0.5	No	SD	_ь
A3	66/F	Melanoma	Lung, liver	1	Yes	0.5 (0.7)	20.3 (4.8)	95 (24)	8	0.6	2.0	No	PD	
A4	60/F	Ovarian cancer	Peritoneum	C	No	5.7 (0.3)	62.3 (5.0)	34 (7)	8	1.5	3.5	No	SD	
A5	67/F	Melanoma	Abdomen	_	No	1.3 (0.7)	55.7 (4.3)	262 (81)	8	2.3	5.0	No	PD	c
A6	56/F	Colon cancer	Lung, liver	C	No	11.1 (2.8)	85.8 (4.5)	47 (11)	8	2.8	5.5	Yes	PD	
Group B (C	GDT non-d	lose escalation/Zol. tr	eatment)											
ВІ	67/M	Melanoma	Adrenal grand, heart	1	No	0.3 (0.1)	15.3 (2.2)	728 (111)	6	0.3	1.0	No	SD	
B2	48/F	Adeno-	Bone	R	No	2.1 (0.5)	53.6 (9.9)	144 (72)	8	0.5	1.1	Yes	PD	
		carcinoma												
B3	47/M	Cholangio-	Local	C	No	1.8 (0.1)	59.5 (4.8)	17 (2)	8	0.4	1.4	No	PD	
		carcinoma	advanced disease				,							
B4	65/F	Melanoma	Lung, abdominal mass	1	No	0.5 (0.1)	12.3 (1.9)	159 (84)	8	0.5	1.4	No	NE	
B5	61/F	Melanoma	Lung	_	No	0.8 (0.0)	71.4 (6.6)	586 (273)	7	1.0	1.7	No	PD	
B6	61/F	Ovarian carcinoma	Peritoneum	C	No	5.1 (0.7)	86.6 (2.0)	43 (7)	8	1.0	3.0	No	PD	
B7	51/F	Colon cancer	Lung, liver	CRI	No	2.6 (0.3)	70.0 (3.8)	86 (14)	8	0.8	3.3	Yes	PD	
B8	57/F	Colon cancer	Lung	C, R	Yes	2.3 (0.1)	64.0 (3.1)	253 (25)	6	1.5	4.6	No	PD	
B9	68/M	Duodenal cancer	Lung	C	No	9.1 (0.4)	71.7 (3.9)	78 (13)	8	2.2	7.2	Yes	PD	
0,	0011	Dooderia Carico	abdomen		140	711 (0.1)	7117 (515)	10 (15)		2.2	/	103	رت	
Group C ((	GDT/Zol. t	reatment with other	therapy)											
Ci	Jun	DI CASE CATICCI	brain, liver, lung	C	Yes	1.3 (0.1)	224 (4.5)	119 (34)	7	0.3	0.9	No	PR	_d
C2	44/F	Breast cancer	Bone, liver	C, R, H	Yes	1.1 (0.1)	24.3 (5.7)	269 (143)	7	1.5	3.6	Yes	CR	_e
C3	33/F	Cervical cancer	Lung, pelvis	C	No	2.3 (1.0)	78.9 (6.9)	160 (32)	8	1.9	4.0	Yes	PR	d

% γδ T in CD3+\*

Abbreviations: C=chemotherapy, CR=complete remission;  $\gamma\delta$  T=V $\gamma9V\delta2$  T cell; H=hormonal therapy, I=immunotherapy, inj.=injection; NE=not evaluable; PD=progressive disease; PR=partial remission; R=radiotherapy; S=surgery, SD=stable disease; ZoI=ZoIedronate: \*Represents the mean (s.e.) from 6-8 vaccines: \*Fever after infusion, AI also had vomiting: \*bLarge bulk of disease but stable. \*No new lesions. \*dWith chemotherapy. \*With hormonal therapy.

Figure 25. Treatment and Clinical Outcomes for Ex Vivo Expansion of Vg9Vd2 T Cells

# INB-200 for Other Oncology Indications and Use in Combination with Other Therapies

As we look to expand the potential applications for INB-200, we intend to evaluate its antitumor activity in other tumors commonly treated with TMZ or other alkylating agents such as darcarbazine or the nitrosoureas. These tumors may include additional brain tumors, melanoma, uveal melanoma, neuroendocrine and adrenal tumors, soft tissue sarcomas, uterine sarcoma, small cell lung cancer, and ovarian cancer, among others.

Based on extensive preclinical data, we also intend to investigate the potential combination of drug resistant gamma-delta T cells with other immune oncology drugs, such as checkpoint inhibitors, which may enhance the immunostimulatory activity of these cells. We also plan to assess the potential of combinations of drug-resistant gamma-delta T cells with inhibitors of DNA damage repair proteins, such as the PARP inhibitors that have been shown to increase the expression of stress signals such as NKG2D ligand expression in tumor cells. Consistent with our previous work, we anticipate that this significant increase in stress signaling may improve the ability of gamma-delta T cells to target these tumors.

# INB-100 for the Treatment of Patients with Hematological Malignancies Undergoing HSCT

INB-100 is an allogeneic DeltEx product candidate created from healthy donors. INB-100 is allogeneic, expanded activated gamma-delta T cells. We are developing INB-100 for the treatment of patients with hematological malignancies that are undergoing HSCT. We are collaborating with Joseph McGuirk, D.O., at the University of Kansas Cancer Center, to conduct an investigator-initiated Phase 1 dose escalation trial of INB-100 to assess the safety and tolerability of INB-100. An expansion cohort is anticipated to follow at the recommended highest tolerable dose. We expect to enroll up to 18 patients in the dose escalation portion of this trial. As of June 30, 2021, we have enrolled six patients in this trial, of whom three have been dosed. A fourth patient was dosed to complete the first cohort subsequent to June 30, 2021.

# Hematological Malignancies Overview

Hematological malignancies are characterized by an abnormal and excessive proliferation of blood cells that invade the bone marrow and then the blood. In some patients, these cancerous cells proliferate rapidly, requiring urgent treatment. These include AML, ALL, chronic myeloid leukemia, or CML and myelodysplastic syndromes, or MDS. There are few treatment options for these patients. One

of the most effective is allogeneic HSCT, where the patient's blood forming cells, including cancerous cells, are first destroyed using chemotherapy, radiation or a combination of both. The patient then receives new bone marrow stem cells from a healthy donor.

Allogeneic Hematopoietic Stem Cell Transplantation Overview

HSCTs are generally for patients with various hematological malignancies where additional therapy can lead to longer-term durability and survival. As depicted in Figure 26 below, the number of HSCT procedures has been increasing over the last 20 years, with more than 9,000 patients treated in the United States in 2018.

The challenge facing many patients who are in need of an allogeneic HSCT is the identification of an appropriately matched donor. Histocompatibility, or tissue compatibility, is the property of having the same, or sufficiently similar, alleles of a set of genes called human leukocyte antigens, or HLAs, between a donor and recipient. Differences in histocompatibility and other tissue antigens between the host and the transferred alpha-beta T cells derived from the donor can trigger a series of potentially life-threatening consequences, such as GvHD. While immunosuppressive drugs can help reduce GvHD, they are not always successful, and their long-term use is associated with multiple complications including leukemic relapse. A match of 8/8 HLA alleles is considered fully matched and is associated with the lowest frequency of GvHD.

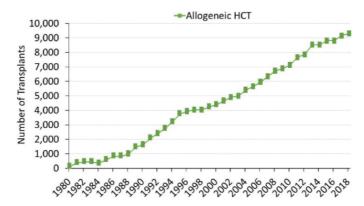


Figure 26. Annual allogeneic HSCT procedures in the United States

In some cases, a donor can be identified who is a close relative and in other cases it may be someone who volunteered to be included in a national donor registry. Because of underrepresentation of the HLA alleles found in many ethnic groups, the probability of identifying a donor with a full match varies widely. Up to 75% of patients of White European descent can find a donor with a full match, but that number drops to 19% for African American patients. Patients who cannot find a fully matched donor must either accept a non-ideal match, which is associated with a higher risk of GvHD, or forgo HSCT entirely. Haploidentical, or partially matched donors, who are relatives, that share alleles with the transplant recipient provide one option for patients lacking a matched donor.

Our Solution — INB-100 for the Treatment of Patients with Hematological Malignancies Undergoing HSCT

We are developing INB-100, an expanded and activated gamma-delta T cell product, with the goal of improving overall survival in patients with hematological malignancies who have undergone allogeneic HSCT. We believe that supplementing the patient's immune system with allogeneic gammadelta T cells will lead to reduced incidence of relapse and improved survival in these patients.

Multiple retrospective studies of leukemia patients treated with alpha-beta TCD allogeneic HSCT showed that high levels of gamma-delta T cells were associated with a significantly higher rate of disease-free survival. In a foundational study led by Dr. Lamb, patients with high levels of gamma-delta T cells had a disease-free survival rate at seven years of over 70% compared to less than 20% for patients with low levels of gamma-delta T cells, which has been supported by subsequent studies. The majority of this effect was observed within six months of treatment. The primary cause of death for patients with low

or normal levels of gamma-delta T cells was leukemic relapse. Often, leukemic relapse is due to a loss of MHC in any residual cancerous cells and gamma-delta T cells may offer a solution as their killing through stress signaling is independent of MHC. Approximately 60% of the high gamma-delta T cell patients who relapsed were still surviving at the time of the publication compared to only 2%, or one patient, with low levels of gamma-delta T cells.

To produce INB-100, we developed and are testing an automated, programmed and functionally closed "point-of- care" manufacturing process that is designed to routinely and cost effectively generate the quantities of the cells required for the treatment of patients. In the past, the high cost for cell therapy and CAR-T therapy has resulted in high prices to patients and a challenging business model towards profitability. Our "point-of-care" manufacturing approach for this program could potentially allow us to take advantage of already available infrastructure, as major academic and transplant centers across the country are building cell manufacturing facilities designed to comply with Good Manufacturing Practice, or GMP, that are often underutilized. This approach could enable us to deliver widespread access to our therapies and reduce costs required to commercialize our products, if successfully developed and approved. As an example, we are utilizing the manufacturing facility at the University of Kansas Cancer Center, the site of our Phase 1 dose-escalation trial with INB-100.

Investigator-Initiated Phase 1 Clinical Trial of INB-100

We are conducting an investigator-initiated Phase 1 dose escalation trial of INB-100 in patients with leukemias who are undergoing allogeneic haploidentical HSCT. The primary endpoints of this trial are safety and tolerability, and secondary endpoints include rates of acute and chronic GvHD, relapse rate and overall survival. Following completion of the dose escalation phase, which we currently expect to be completed in 2022, our goal is to enroll nine to 12 patients, with the ability to enroll up to 18 patients if clinically necessary, in an expansion cohort where they will be followed for up to a year.

INB-100 is prepared from peripheral blood cells, while in parallel, patients undergo HSCT. As depicted in Figure 27 below, INB-100 cells are administered post-engraftment with the goal of providing immunity during the period of immune cell reconstitution.

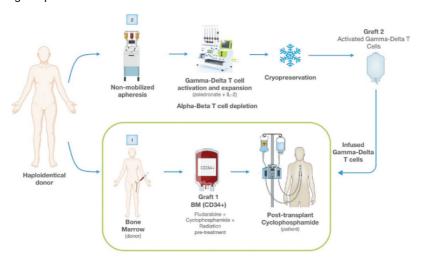


Figure 27. INB-100 Administration

As depicted in Figure 28 below, patients will initially be treated using a standard HSCT protocol, originally developed at Johns Hopkins University, or the Hopkins protocol, under which these patients undergo myeloablative therapy using chemotherapeutic agents that destroy their tumor cells as well as their healthy immune cells. They then undergo allogeneic bone marrow transplant. Prior to the bone marrow transplant, donors will undergo leukapheresis to provide the starting material for INB-100 at least seven days ahead of the transplant. The INB-100 starting material will then be prepared and cryopreserved. After approximately 15 to 20 days, hematopoietic stem cells from the donor engraft in the patient's bone marrow and begin reconstituting the immune system. While the Hopkins protocol has

decreased the risk of GvHD, there is also a reduced anti-leukemic effect. Accordingly, the rate of leukemic relapse has increased to approximately 51% at one year. Within five days of neutrophil engraftment, our INB-100 product candidate will be thawed and administered as a single weight-based dose, leading to an increase in the levels of gamma-delta T cells and potentially providing greater anti-leukemic effect.

As of December 2020, with the increase of COVID-19 infections across the United States, additional enrollment in this clinical trial has been delayed. With the ongoing COVID-19 pandemic, there was an increasing risk that a patient could undergo a conditioning 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 submitted to the FDA and the IRB a modified clinical protocol to allow the usage of previously frozen HSCs. This allows us to perform leukapheresis and to harvest HSCs from the donor and confirm a negative COVID-19 result prior to initiating the myeloablation of the patient. We have been cleared to resume enrollment in this trial pursuant to the amended protocol following the implementation of any required changes.

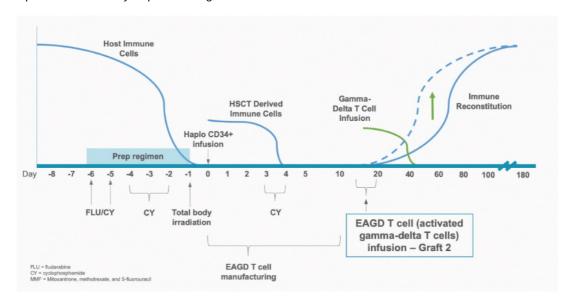


Figure 28. The Projected Composition of Immune Cells in the INB-100 Phase 1 Trial

As represented in Figure 29 below, as of June 30, 2021, six patients have been enrolled in this trial to date in the first dose cohort, three of whom have been infused with INB-100, our DeltEx Allo therapeutic candidate. The six subjects ranged between 44 to 73 years of age. Three subjects were dosed with INB-100 and one subject (001) died prior to receiving INB-100 due to cardiogenic shock most likely from post-HSCT cyclophosphamide.

The first subject to receive INB-100 was patient 002, a 54 year-old female with high risk AML including multiple cytogenetic abnormalities consistent with a poor prognosis. She received the INB-100 infusion in May 2020. This patient achieved full engraftment with 100% chimerism. Day 60 and 100 post-HSCT safety observation periods passed without the occurrence of grade 3+ acute GvHD. Patient 002 subsequently developed a rash which was later determined to possibly be grade 2 skin GvHD related to the INB-100 infusion or to the HSCT as the donor previously had a skin condition. This rash has resolved and the patient is off of any steroids. A cytogenetic abnormality was observed at post-transplant follow-up resulting in tapering of immune suppression and initiation of maintenance chemotherapy. As of June 30, 2021, this patient was at day 442 or 14.5 months post-HSCT and remained in remission of their leukemia with 100% donor chimerism.

Patient 003 is a 45 year-old female with intermediate risk AML. She was treated with an INB-100 infusion in July 2020 and reached 100% chimerism by day 43 post-HSCT. She did not experience any

grade 3 acute GvHD at the 60 and 100 day safety observation periods but developed gastrointestinal related grade 2 GvHD approximately 7 weeks post-HSCT and 5 weeks post INB-100 infusion. This event resolved with treatment and was possibly related to HSCT and the INB-100 infusion. As of June 30, 2021, this patient is past a year without relapse, having remained on study at day 370 or 12.2 months post-HSCT in continuous complete remission with no further evidence of GvHD.

Patients 004 and 005 were enrolled, but a product could not be manufactured due to a manufacturing complication. In order to prevent future delays, we relocated clinical trial product manufacturing to an academic GMP facility closer to our laboratory headquarters in Birmingham, Alabama, which provides us with direct access and closer collaboration with the facility's manufacturing staff.

Patient 006 is a 66 year-old male with high-risk relapsed AML. The patient has undergone HSCT and a product has been successfully manufactured. This patient engrafted in July 2021 and received an infusion of INB-100.

No severe treatment-emergent or infusion related adverse events have been reported in this trial to date.

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.

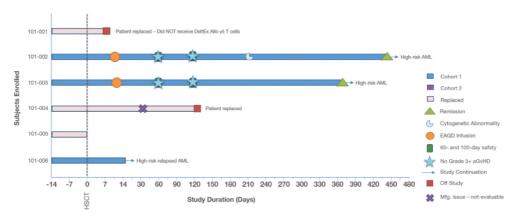


Figure 29. Summary of Patients Enrolled in INB-100 Phase 1 Trial

# **INB-100 Preclinical Studies**

Animal studies and indirect evidence from human allogeneic transplant studies suggest that gamma-delta T cells can facilitate engraftment, which may translate into faster reconstitution of the immune system. In a murine allogeneic transplant model, donor gamma-delta T cells facilitated the engraftment of TCD donor bone marrow. When TCD donor marrow was supplemented with up to  $3x10^6$  gamma-delta T cells prior to infusion into mismatched recipients, donor chimerism increased by approximately 40%. A separate study revealed similar findings in MHC-mismatched mice, and later demonstrated that the gamma-delta T cell dose necessary to facilitate engraftment did not result in lethal murine GvHD. Improved engraftment was also observed in lethally irradiated rats reconstituted with  $1x10^8$  alpha-beta T cell depleted bone marrow, suggesting that gamma-delta T cells are able to facilitate improved engraftment even in the absence of alpha-beta T cells. In this study, all rats engrafted with a mean of 92% ( $\pm$  4%) donor cells and showed no clinical evidence of GvHD. Studies comparing patients who received alpha-beta TCD grafts with those receiving pan-TCD grafts also show a positive association between the number of gamma-delta T cells in the graft and less time to engraftment.

Both murine and human studies suggest that gamma-delta T cells are not primary initiators of GvHD and may in fact modulate the GvHD activity of alpha-beta T cells. Indeed, large doses of expanded gamma-delta T cells have been infused into lethally irradiated MHC-disparate mice without causing GvHD. Although it has been observed that gamma-delta T cells have activated GvHD response, the investigators reporting this study found no direct evidence that GvHD was initiated by gamma-delta T cells. In two separate human trials, it was observed that gamma-delta T cells were not substantially

activated in the *in vitro* allogeneic mixed lymphocyte culture. Several studies post-HSCT have shown transient increases in gamma-delta T cells, but have not associated this finding with GvHD. Studies comparing outcomes of patients that received alpha-beta T cell depleted grafts with pan-T cell depleted grafts all showed a lower incidence of GvHD in the alpha-beta T cell depleted group, suggesting that infusion of gamma-delta T cells in the graft does not subject the recipient to increased risk of GvHD. Whether gamma-delta T cells are truly less likely to contribute to the development of GvHD and the contribution of any residual alpha-beta T cells in the graft remains untested. However, from the above reasoning, it is logical to propose that in future studies, gamma-delta T cells might indeed be introduced in the setting of allogeneic HSCT, specifically to provide innate anti-tumor effect with only minimal risk of GvHD.

# **Future Development for Our Lead Product Candidates**

Our goal is to ultimately treat solid tumor cancers with an allogeneic cellular immunotherapy. Delivering a previously manufactured and cryopreserved therapeutic product from donor to patient could have the ability to create a product that is produced and sold as "off-the-shelf." We believe this could improve the availability of cell therapy products, as well as potentially reduce the cost of the product to both us and to the patients. Ultimately a donor-derived product may be superior to a patient-derived product, as cells can be harvested and manufactured from younger, healthy individuals who do not have a potentially immune-suppressive tumor impacting the function of their immune cells. The goal of an allogeneically delivered product for solid tumor cancers is complex and we are not aware of any solid tumor cancers currently treated with transplant or lymphodepletion protocols.

The necessity to add transplant and lymphodepletion protocols increases the complexity of treatment due to the risk of potentially fatal GvHD from HLA-mismatched cells in the solid tumor setting. Further, this may also bring to question the direct impact of the lymphodepleting regimen on the tumor itself. In our INB-200 program for GBM, the standard-of-care chemotherapy with TMZ is our lymphodepleting regimen and has been in use in this setting for over 16 years.

To reach our goal of creating an allogeneic genetically modified product candidate for solid tumors, we are pursuing two clinical protocols that could provide the data required for applicable regulatory filings. INB-100 is an unmodified, allogeneic product candidate tested in the transplant setting, results from which will help assess the risk of GvHD from HLA-mismatched gamma-delta T cells, or potentially any residual alpha-beta T cells that may remain. INB-200 is an autologous, genetically modified gamma-delta T cell product candidate that tests the safety and efficacy of our DRI approach in our first solid tumor indication. Our goal is to combine the prior safety data from both of the ongoing clinical trials for INB-200 and INB-100 in order to create the regulatory package for an allogeneic-sourced product for the treatment of GBM and other solid tumor cancers.

#### **Our Additional Product Candidates**

# INB-400: Allogeneic Drug-Resistant Gamma-Delta T Cells

INB-400 is our allogeneic genetically modified product candidate, or DeltEx DRI for solid tumor cancers. We initially we intend to develop INB-400 in a treatment protocol similar to INB-200, in newly diagnosed GBM, but with allogeneically sourced gamma-delta T cells as shown below in Figure 30. Our primary goal with INB-200 is to demonstrate the antitumor activity of our technology in a difficult-to-treat solid tumors, such as GBM. Initially, we eliminated the additional risk and complexity of GvHD complications in allogeneic cell therapies by using autologous cells. Based on preclinical data, we anticipate that there will be a low risk of patients developing GvHD upon administration of an allogeneic gamma-delta T cell product candidate. We expect that results obtained from our INB-100 clinical program, in which gamma-delta T cells are expanded and activated using a process similar to that used for INB-200, will help inform our assessment of the risk of GvHD with our allogeneic gamma-delta T cell product candidates, such as INB-400. Assuming that the FDA agrees with our assessment, and we receive authorization to proceed under an IND, we intend to use cells from healthy donors to develop INB-400. We are initially developing INB-400 to treat newly diagnosed GBM and we expect to submit an IND by first half of 2022, dependent on FDA guidance and anticipated safety data from our ongoing Phase 1 clinical trials in INB-200 and INB-100.

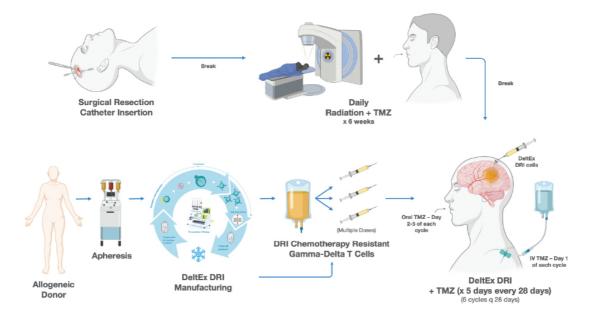


Figure 30. INB-400 Administration

# INB-300: Drug-Resistant CAR Gamma-Delta T Cells

INB-300 is our DeltEx DRI and CAR gamma-delta T cell preclinical product candidate that combines our expertise in gamma-delta T cells, our DeltEx DRI technology and a novel CAR directed against the chlorotoxin peptide. Chlorotoxin is a 36-amino acid peptide isolated from the venom of Leiurus quinquestriatus, the deathstalker scorpion. The GBM-binding potential of chlorotoxin was first identified through conjugation with the radioisotope and subsequently developed as a tumor paint. Chlorotoxin binds broadly and specifically to GBM while showing minimal off-target binding to normal brain tissues. Chlorotoxin has also been observed to bind multiple solid tumor cancers, including lung, breast and prostate cancers, among others. We have developed a signaling, or cytotoxic, and nonsignaling chlorotoxin CAR-T construct that incorporates the gene for MGMT from INB-200, our DeltEx DRI candidate, as shown in Figure 31 below. This CAR-T construct is designed to confer both TMZresistance and GBM-targeting capability to transduce gamma-delta T cells. In vitro testing reveals that MGMT-chlorotoxin CAR-modified Jurkat T cell lines specifically bind GBM cell lines and upregulate CD69, indicating CAR-associated activation. We have also created more advanced constructs that include dual chlorotoxin-binding domains that also incorporate the DeltEx DRI technology. Early data show that our new constructs generated synergies with significantly greater CD69 activation than expected from the activity of a single chlorotoxin domain. We are currently transducing the MGMTchlorotoxin-CAR into gamma-delta T cells and have documented CAR-T expression. We continue to generate animal data to support continued development.

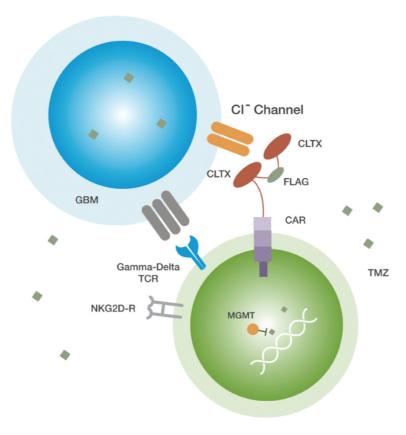


Figure 31. INB-300, a DeltEx DRI, Dual Chlorotoxin (CLTX) CAR

#### **License Agreements**

# Exclusive License Agreement with Emory University, Children's Healthcare of Atlanta, Inc. and The UAB Research Foundation

In June 2016, we entered into an Exclusive License Agreement with the Emory University, Children's Healthcare of Atlanta, Inc. and The UAB Research Foundation, or UABRF, as amended from time to time, which we refer to as the Emory license agreement. We amended the Emory license agreement in October 2017 and July 2020. Under the Emory license agreement, we obtained an exclusive worldwide license under certain immunotherapy-related patents and know-how related to gamma-delta T cells developed by the Emory University, Children's Healthcare of Atlanta, Inc. and UABRF's affiliate, UAB, 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 to us under the Emory license agreement, we paid Emory a nominal upfront payment. We are required to pay Emory 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 of \$0.5 million beginning in the third year following the first sale of a licensed product, increasing to \$1.0 million in the fourth year and \$1.5 million in the fifth year and thereafter. In addition, we are also required to pay Emory between 1% and 15% of any fees or payments we may receive from our sublicensees, depending on when the sublicense executed. In the event no milestone payments have been paid in certain years, we will be required to pay an annual license maintenance fee: prior to the 78th-month anniversary of the agreement, \$250,000; prior to the 90th-month anniversary of the agreement, \$0.5 million; and on or after the eight-year anniversary of the agreement, \$1.0 million. The Emory license agreement also requires us to reimburse Emory for the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the Emory license agreement, we are required to use our best efforts to develop, manufacture and commercialize the licensed product, and are 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. We may terminate the Emory license agreement at will at any time upon prior written notice to Emory. Emory has the right to terminate the Emory license agreement if we materially breach the agreement (including failure to meet our diligence obligations) and fail to cure such breach within specified cure period, if we become bankrupt or insolvent or decide to cease development and commercialization of the licensed product, or if we challenge the validity or enforceability of any licensed patents. For more information related to the intellectual property acquired pursuant to the Emory license agreement, see the section titled "Business—Intellectual Property."

## **Exclusive License Agreement with UABRF**

In March 2016, we entered into an Exclusive License Agreement with UABRF, as amended from time to time, which we refer to as the UABRF license agreement. We amended the UABRF license agreement in December 2016, January 2017, June 2017 and November 2018. Under the UABRF license agreement, we 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 cell therapies developed by UAB 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 to us under the UABRF license agreement, we paid UABRF a nominal upfront payment and issued 91,250 shares of our common stock to UABRF, which were subject to certain antidilution rights. The antidilution provision required us to issue additional shares of common stock such that UABRF maintained a 2.5% ownership interest in the company until we raised at least \$20.0 million through one or more rounds of investment. As of August 2020, we raised an aggregate of \$36.6 million through the sale of our securities. Between March 2017 and August 2020, we issued UABRF an additional 151,382 shares of our common stock in satisfaction of this antidilution provision. Accordingly, beginning in September 2020, the shares held by UABRF may be diluted only upon the same terms and conditions of certain founders until the completion of our initial public offering.

In addition, we are 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 our net sales of the licensed products, low single-digit running royalties on net sales of the licensed products by our sublicensees, and a share of certain non-royalty income ranging between 2.5% to 25%, depending on the status of certain clinical trials, that we may receive, including from any sublicensees. The UABRF license agreement also requires us to reimburse UABRF for the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the UABRF license agreement, we are 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. We 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 we materially breach the agreement and fail to cure such breach within a specified cure period, if we fail to diligently undertake development and commercialization activities as set forth in the development and commercialization plan, if we underreport our payment obligations or underpay by more than a specified threshold, if we challenge the validity or enforceability of any licensed patents, or if we become bankrupt or insolvent. For more information related to the intellectual property acquired pursuant to the UABRF license agreement, see the section titled "Business—Intellectual Property."

## Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We plan to build focused capabilities in the United States to commercialize our

development programs focused on allogeneic or autologous, genetically modified gamma-delta T cell therapies for the treatment of cancer, where the patient populations and medical specialists for the indications we are targeting are sufficiently concentrated to allow us to effectively promote our products, if approved for commercial sale, with a targeted sales team. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

## Manufacturing

We do not own or operate manufacturing facilities for the production of our current product candidates. We currently rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices, active pharmaceutical ingredients, lentiviral vectors and finished product for our preclinical research and clinical trials. We have an agreement with an academic GMP cell therapy lab to manufacture product candidates for our Phase 1 clinical trials. The multi-year agreement allows our medical technologists direct access to the facility to assist the GMP facility staff. The agreement provides for manufacturing on a per-patient basis, We do not have any current contractual relationship for the manufacture of Phase 2/3 clinical trials or commercial supplies. We intend to enter into agreements with third-party contract manufacturers and one or more backup manufacturers for future production. We are analyzing the feasibility of building manufacturing capabilities for future development and commercial quantities of any products that we develop. Such products will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval.

# Competition

The biotechnology industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. We believe that our proprietary gamma-delta T cell platform and our product candidates, strategic collaborations and scientific and clinical expertise may provide us with competitive advantages. However, we face potential competition from various sources, including larger and betterfunded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions. The key competitive factors affecting the success of any product that may be approved by regulators will include the efficacy, safety profile, pricing, method of administration and level of promotional activity.

Our competitors in the field of gamma-delta T cell therapy include Adaptate Biotherapeutics Ltd, American Gene Technologies International Inc., CytoMed Therapeutics Pte Ltd, Editas Medicine, Inc., Enochian BioSciences, Inc. GammaDelta Therapeutics Limited, ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Lava Therapeutics B.V., Leucid Bio Ltd, PhosphoGam Inc., Sandhill Therapeutics, Inc. and Shattuck Labs, Inc., all of which remain preclinical. Four competitors, Adicet Bio, Inc., Avalon Globocare Corp., Gadeta BV and TC BioPharm Limited, have initiated Phase 1 clinical trials. Our gamma-delta T cell product candidates may also compete with other cell and molecule-based immunotherapy approaches using and/or targeting natural killer cells, T-cells and dendritic cells.

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. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective, or more effectively marketed and sold, than any treatment we may commercialize and they may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our treatments.

Mergers and acquisitions in the biotechnology and pharmaceutical 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 study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new therapies enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have a better safety profile, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market

# **Intellectual Property**

#### Overview

We actively seek to protect our proprietary technology, inventions, improvements to inventions and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also may rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on future in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of gene therapy that may be important for the development of our business. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent-term extensions where available.

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 issued patent in Australia, one allowed patent application in Israel, eight pending U.S. applications 47 other foreign national-stage applications, including four European regional-phase applications that are important to the development of our business.

Our policy is to file patent applications to protect proprietary technology, inventions and improvements to inventions and other intellectual property that may be commercially important to the development of our business. We also intend to seek additional patent protection or rely upon trade secret rights to protect other technologies that may be used to manufacture and develop our gammadelta T cell products. We are a party to exclusive license agreements that grant us rights to use specific technologies in our gamma-delta T cell products and in the manufacturing and development of our products. For more information, see the section titled "Business—License Agreements."

#### **Our Patent Portfolio**

Patent applications directed to our most advanced programs are summarized below.

INB-200

Pursuant to the Emory license agreement, we have licensed two issued U.S. patents, two issued European patents (each which have been widely validated in Europe), one allowed European patent application and one U.S pending patent application. These patents and applications contain claims or supporting disclosures directed to the INB-200 composition of matter and to methods of treating diseases of interest using INB-200. Issued patents and patents issuing from the pending applications, if any, are expected to expire in 2030, without accounting for potential patent term extensions and adjustments.

INB-200 and Immune Checkpoint Inhibitor Combination Therapy

We co-own one pending U.S. patent application, one issued Australian patent and nine other national stage patent applications including a European regional phase application with The UAB

Research Foundation. These patents and applications contain claims or supporting disclosures directed to methods of treating diseases of interest using INB-200 in combination with immune checkpoint inhibitor therapies. Patents issuing from these patent applications, if any, are expected to expire in 2037, without accounting for potential patent term extensions and adjustments.

# INB-200 and PARP Inhibitor Combination Therapy

We own one pending U.S. patent application and eight other foreign national stage applications that contain claims or supporting disclosures directed to methods of treating diseases of interest using INB-200 in combination with PARP inhibitor therapies. Patents issuing from these patent applications, if any, are expected to expire in 2039, without accounting for potential patent term extensions and adjustments.

## INB-100

Pursuant to the UABRF license agreement, we have licensed one U.S patent application and 10 foreign national-stage applications, including a European regional phase application. These patent applications contain claims or supporting disclosures directed to the INB-100 composition of matter and to methods of treating diseases of interest using INB-100. Patents issuing from these patent applications, if any, are expected to expire in 2036, without accounting for potential patent term extensions and adjustments.

#### INB-300

Pursuant to the UABRF license agreement, we have also licensed one pending U.S. patent application and nine foreign national-stage applications, including a European regional phase application. These patent applications contain claims or supporting disclosures directed to the INB-300 composition of matter and to methods of treating diseases of interest using INB-300. Patents issuing from these patent applications, if any, are expected to expire in 2037, without accounting for potential patent term extensions and adjustments.

We also own two pending U.S. provisional application that contains claims or supporting disclosures directed to additional INB-300 compositions and to methods of treating diseases of interest. Patents issuing from this patent application, if any, are expected to expire in 2042, without accounting for potential patent term extensions and adjustments.

#### Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. In addition, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual

property rights of others, which could materially harm our business. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

#### Trade Secrets and Know-How

We also rely on trade secrets, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary processes for expanding and activating therapeutic quantities of gamma-delta T cells and modified gamma-delta T cells. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and others who may have access to proprietary information, under which they are bound to assign to us inventions made during the term of their employment or term of service. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

# **Government Regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin
  and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each treatment site before the trial is commenced;
- performance of adequate and well controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or
  facilities at which the proposed product is produced to assess compliance with cGMP and to
  assure that the facilities, methods and controls are adequate to preserve the biological
  product's continued safety, purity and potency, and of selected clinical investigation sites to
  assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

#### Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Supervision of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or
  patients with the target disease or condition. These studies are designed to test the safety,
  dosage tolerance, absorption, metabolism and distribution of the investigational product in
  humans, the side effects associated with increasing doses, and, if possible, to gain early
  evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a
  specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing
  schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2
  clinical trials may be conducted to obtain information prior to beginning larger and more
  expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to

further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so- called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

# **BLA Submission and Review**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies, and the sponsor of an approved BLA is also subject to an annual program fee.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured, including, as applicable, for compliance with Good Tissue Practices. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more treatment sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require postmarketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

# **Expedited Development and Review Programs**

The FDA offers a number of expedited development and review programs for qualifying product candidates, including fast track designation, breakthrough therapy designation, accelerate approval and priority review. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA and the payment of applicable user fees, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. Such a product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product 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 includes all of the fast track program features, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or lifethreatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has 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. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well controlled post-marketing clinical studies to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

In 2017, FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it gualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review and approval will not be shortened.

# **Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic 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. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective, if the second applicant demonstrates its product is clinically superior to the approved product with orphan exclusivity, or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation may also entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

# Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP. which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply

with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

## Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several quidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

# Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and

local governments. For example, research, sales, marketing activities and scientific/educational grant programs must have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, transparency laws, the health information privacy and security laws, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal false claims laws, including the False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions and civil monetary penalty laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Additionally, companies have been prosecuted for, among other things, causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Further, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The Health Insurance Portability and Accountability, or HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, as well as independent contractors, or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates and their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In addition, many states and foreign jurisdictions have enacted analogous versions of these laws. For example, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts. Further, some states require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance and restrict marketing practices or require disclosure of marketing expenditures and pricing information. State and foreign laws may also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. In particular, 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, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, the California Consumer Privacy Act of 2018, or CCPA came into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies.

In addition, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area or EEA or the United Kingdom, or otherwise carried out in the context of EEA or United Kingdom establishments (regardless of where any processing in question occurs), including personal data related to health and genetic information, is subject to the GDPR including, where relevant, as implemented in the United Kingdom. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data. For more information, see the section titled "Risk Factors—Risks Related to Commercialization and Regulatory Compliance."

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose

requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Additionally, if any of 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 civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs.

#### Coverage, Pricing and Reimbursement

In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining coverage and reimbursement approval of a product from a thirdparty payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In particular, obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of reimbursement will be adequate. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs), such as our product candidates, once approved, may be eligible for coverage under Medicare Part B. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program.

# Healthcare Reform

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 the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now
  agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to
  eligible beneficiaries during their coverage gap period, as a condition for the manufacturers'
  outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to
  offer Medicaid coverage to additional individuals and by adding new mandatory eligibility
  categories for individuals with income at or below 133% of the federal poverty level, thereby
  potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;

- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow on biologic products.

By way of example, in December 2017, the Tax Act was enacted which repealed, effective January 1, 2019, the tax penalty for an individual's failure to maintain ACA-mandated health insurance, commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. 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 is 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. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013. Additionally, due to subsequent legislative amendments to the statute, including the BBA, the reductions will stay in effect through 2030, other than a temporary suspension from May 1, 2020 through December 31, 2021 due to the ongoing COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. 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 Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Further, at the states level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Further, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic.

# The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

#### **Environmental Regulation**

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

#### Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

# **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.

#### **Facilities**

We lease approximately 600 square feet of office space for our principal executive offices, which are located at 79 Madison Avenue, New York, New York 10016, under an operating lease that expires on August 31, 2021, with the option to renew for an additional period upon the expiration of this lease. We also lease approximately 2,500 square feet of laboratory and office space, which is located at 1500 First Avenue North, Birmingham, Alabama 35203, under an operating lease that currently expires on September 1, 2021, which automatically renews for a period of an additional 12 months upon the expiration of the initial term, but which can be terminated by us upon 60 days notice. We have also leased approximately 9,000 square feet of space located in the Martin Biscuit Building in Pepper Place, 2901 2nd Avenue South, Birmingham, Alabama. We are developing approximately 5,250 square feet of laboratory space, as well as approximately 3,700 square feet of office, conference and potentially modular GMP manufacturing space. The lease is a 63-month term, expiring on February 17, 2026 and has an option for a five-year extension. Our Birmingham facilities are both located within Qualified Opportunity Zones as defined in Section 1400Z-2 of the Internal Revenue Code. We will seek to use commercially reasonable efforts to expand our facilities within Qualified Opportunity Zones as long as it remains consistent with the best interests of the Company. We believe that our facilities are adequate to meet our current needs and that additional space can be obtained on commercially reasonable terms as needed.

# **Employees and Human Capital Resources**

As of June 30, 2021, we had 13 full-time employees, of whom eight were primarily engaged in research and development activities. A total of five employees have an M.D. or Ph.D. degree. None of our employees are represented by a labor union and we consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

#### **MANAGEMENT**

The following table sets forth information regarding our executive officers and directors, including their ages as of July, 2021:

NAME	AGE	POSITION(S)
Executive Officers		
William Ho	45	President, Chief Executive Officer and Director
Lawrence Lamb, Ph.D.	67	Executive Vice President and Chief Scientific Officer
Patrick McCall	38	Chief Financial Officer
Kate Rochlin, Ph.D.	40	Vice President, Operations and Innovation
Non-Employee Directors		
Alan S. Roemer <sup>(1)(2)</sup>	51	Chairman
Peter Brandt <sup>(1)(3)</sup>	64	Director
Emily T. Fairbairn <sup>(3)</sup>	59	Director
Luba Greenwood <sup>(1)(2)</sup>	42	Director
Travis Whitfill <sup>(2)(3)</sup>	31	Director

- (1) Member of the Audit Committee
- (2) Member of the Compensation Committee
- (3) Member of the Nominating and Corporate Governance Committee

#### **Executive Officers**

William Ho is our co-founder, and has served as our President, Chief Executive Officer and director since our inception in November 2015 and also served as our Chief Financial Officer from October 2020 to January 2021. Prior to this, from April 2014 to November 2017, Mr. Ho was the founder and Managing Partner at AlephPoint Capital, a private healthcare fund. Prior to AlephPoint, Mr. Ho launched the public investments and cross-over portfolio at New Leaf Venture Partners, a leading healthcare venture capital firm, and served as its Public Investment Director from 2010 to 2014. Previously, Mr. Ho also served as a Senior Equity Research Analyst at Bank of America from 2006 to 2009 and an Equity Research Analyst at Piper Jaffray & Co. from 2003 to 2006, covering the biotechnology and life-science tools sectors. Earlier in his career, Mr. Ho was responsible for FP&A and operational analysis at CuraGen Corporation and worked as an Associate on the Healthcare Investment Banking team at Cowen. Mr. Ho was an inductee into the McMaster University Alumni Gallery in 2020 and currently serves as a member of their Dean's Advisory Board for the Faculty of Science. Mr. Ho received an MBA from the University of Notre Dame and a B.S. in Biochemistry from McMaster University. We believe that Mr. Ho's extensive knowledge of our company as founder, President and Chief Executive Officer and his experience in the healthcare industry qualifies him to serve on our board of directors.

Lawrence Lamb, Ph.D. is our co-founder and has served as our Executive Vice President and Chief Scientific Officer since November 2018 and as the Chair of our Scientific Advisory Board since December 2017. From April 2004 to December 2018, Dr. Lamb was a Professor of Medicine at the University of Alabama at Birmingham, or UAB, specializing in transplantation immunology, and also served as the Director of the UAB Cell Therapy Laboratory in the Bone Marrow Transplant and Cellular Therapy department. Prior to that, from 1995 to 2004, he served as a Professor of Medicine at the University of South Carolina School of Medicine. Dr. Lamb currently serves on several national and international committees related to cell and gene therapy. Dr. Lamb received two postdoctoral fellowships, one from University of South Carolina-Columbia and another from South Carolina Cancer Center. He also received a Ph.D. and an M.S. from University of South Carolina-Columbia and a B.S. from Medical College of Georgia.

**Patrick McCall** has served as our Chief Financial Officer since February 2021. Prior to joining IN8bio, Mr. McCall served as Vice President of Finance at Turnstone Biologics Corp., an international

clinical-stage biotechnology company focused on cancer immunotherapies, from November 2018 to January 2021. From January 2018 until November 2018, Mr. McCall was the Corporate Controller at Catalyst Biosciences, a publicly traded, clinical-stage biopharmaceutical company focused on developing hemophilia treatments. Previously, he served as Catalyst's Director of Accounting and Finance from October 2015 to January 2018. Prior to that, Mr. McCall served as a Senior Manager of Technical Accounting at LendingClub Corp., as a Corporate Financial Reporting Manager at Apple Inc. and as a Manager of Financial Reporting at Chubb Limited. Mr. McCall is an active Certified Public Accountant (CPA) and holds an MBA from Cornell University and a B.S. in Accounting from Drexel University.

Kate Rochlin, Ph.D. has served as our Vice President of Operations and Innovation since December 2020, and previously served as our Associate Vice President of Operations and Innovation from August 2020 until December 2020. Since February 2013, Dr. Rochlin has served as a Project Principle of the Solution Lab, Inc., a nonprofit organization that provides Ph.D. and MBA students real-world consulting experiences, and since October 2019 she has also served on the Solution Lab's board of directors. From March 2020 until August 2020, Dr. Rochlin served as the Chief Business Officer of Curadigm SAS, a private nanotechnology company. Previously she served as Curadigm's Director of Business Development from March 2019 to August 2020. Prior to that, Dr. Rochlin Served as Director of Scientific Affairs for Filament BioSolutions Inc., a private biotechnology company, from March 2016 until March 2019. From September 2012 to January 2017, she was a Co-founder and the Chief Scientific Officer of Immunovent, LLC, a biotechnology company focused on commercialization of technologies for diagnosing allergies, and then served as a Scientific and Business Advisor to Immunovent, LLC from January 2017 until March 2019. Dr. Rochlin received a Ph.D. in Cell and Developmental Biology from Weill Cornell University, and a B.A. with double majors in Molecular Biology and History and Sociology of Science (HSSC) from the University of Pennsylvania.

# **Non-Employee Directors**

Alan S. Roemer, MBA, MPH has served as chairman and a member of our board of directors since September 2020. Mr. Roemer has served on the board of directors and as the chair of the audit committee of board of NexImmune, Inc., a public biotechnology company, since February 2017. He has served as chairman of the board of UTILITY therapeutics Ltd., a private biotechnology company, since March 2020. Mr. Roemer was a founding leadership team member and senior vice president of Roivant Sciences, Inc., a private biopharmaceutical company, from the company's inception May 2014 to August 2019, where he held various senior management roles responsible for finance, operations and corporate development. From March 2015 to August 2015, he also served as principal financial and accounting officer of Axovant Sciences Ltd., a public biopharmaceutical company, and a founding leadership team member and chief financial officer of its wholly owned subsidiary, Axovant Sciences, Inc. Mr. Roemer also served as a member of the board of directors of SomPharmaceuticals SA, a private biopharmaceutical company, from August 2012 to May 2016, until its acquisition by Amryt Pharma plc. Prior to Roivant and Axovant, Mr. Roemer served in various executive roles, including managing director of the Trout Group LLC and Trout Capital LLC from 2009 to 2014, chief financial officer and treasurer of Zelos Therapeutics, Inc. from 2008 to 2009, and vice president of Pharmasset, Inc. 1999 to 2008, which was subsequently acquired by Gilead Sciences, Inc., where he was the first full-time management team member. Mr. Roemer has also served as a member of the business advisory board of Envisagenics, Inc., a private artificial intelligence company, since March 2020, and a member of the board of trustees of the Helene Fuld College of Nursing since June 2014. Mr. Roemer received a B.S. in Business Administration from Georgetown University and his MBA and MPH degrees from Emory University's Goizueta Business School and Rollins School of Public Health. We believe that Mr. Roemer's significant executive and board leadership experience in the biopharmaceutical industry qualifies him to serve on our board of directors.

**Peter Brandt** has served as a member of our board of directors since July 2019. Since June 2015, Mr. Brandt has served as the Chairman Rexahn Pharmaceuticals, Inc., a public biotechnology company, and as a member of Rexahn's board of directors since September 2010. From 2011 to 2013, Mr. Brandt served on the board of directors, and as Chairman from December 2012, of ePocrates, Inc., a point of care medical applications company (until its acquisition by athenahealth, Inc.). From 2011 to 2012, Mr. Brandt also served as interim Chief Executive Officer and President of ePocrates, Inc. Prior to that.

from 2008 to 2009, Mr. Brandt served as President, Chief Executive Officer, and as a member of the board of directors of Noven Pharmaceuticals, Inc., a specialty pharmaceutical company (until its acquisition by Hisamitsu Pharmaceutical Co., Inc.). Prior to leading Noven, Mr. Brandt spent 28 years at Pfizer Inc. where he served various roles, including as Pfizer's President—U.S. Pharmaceuticals Operations, where he helped deliver revenue and earnings growth while engineering major change within Pfizer's U.S. pharmaceuticals organization. Prior to running U.S. operations, he led Pfizer's Latin American pharmaceuticals operations, as well as the following Pfizer Worldwide Pharmaceuticals functions: finance, information technology, planning and business development. He also oversaw the operations of Pfizer's care management subsidiary, Pfizer Healthcare Solutions. Mr. Brandt also served as a director of Auxilium Pharmaceuticals, Inc. from December 2010 to January 2015 (until its acquisition by Endo International PLC). Mr. Brandt received a B.A. from the University of Connecticut and an MBA from the Columbia School of Business. We believe that Mr. Brandt's broad operational management experience in the life sciences industry and experience serving on numerous boards of directors of life sciences companies qualifies him to serve on our board of directors.

*Emily T. Fairbairn* has served as a member of our board of directors since July 2021. Since March 2018, Ms. Fairbairn has served a member of the board of directors, and as chair of the board, of Movano Inc., a health-focused technology company. From 1999 to 2018, Ms. Fairbairn was the cofounder and CEO of Ascend Capital, a hedge fund focused on managing assets for institutional clients such as pensions, endowments and public companies. Prior to founding Ascend Capital, Ms. Fairbairn managed equity portfolios for high net worth clients for Merrill Lynch and, prior to that, worked as a process engineer and supervisor for Pepsi's Frito-Lay brand. Ms. Fairbairn received her B.S. in Chemical Engineering from California State Polytechnic University Pomona. We believe that Ms. Fairbairn's expertise in investment and finance matters and her extensive executive leadership and management experience qualify her to serve on our board of directors.

Luba Greenwood has served as a member of our board of directors since July 2021. Since December 2020, Ms. Greenwood has served as Managing Partner of Binney Street Capital, LLC, a venture capital fund established by the Dana-Farber Cancer Institute, and since 2019 she has served as CEO of LUCA Biologics, Inc., a women's health and microbiome company. From April 2019 to December 2020, Ms. Greenwood served as senior advisor to the CEO of the Dana-Farber Cancer Institute. From October 2018 to February 2021, Ms. Greenwood served as a consultant to Brooklyn ImmunoTherapeutics, Inc. and joined its board of directors in March 2021. From February 2018 to July 2019, Ms. Greenwood was the head of strategic business development and corporate ventures for Verily Life Sciences LLC, a research subsidiary of Alphabet Inc. focused on life sciences and healthcare. From 2015 to February 2018, Ms. Greenwood was the vice president of global business development and mergers and acquisitions at F. Hoffmann-La Roche Ltd., a multinational healthcare company, as well as the head of the Roche Diagnostics Innovation Center, East Coast. Beginning in 2021, Ms. Greenwood has also served on the board of directors of OS Acquisition Corp., a blank check company. Ms. Greenwood received a B.A. in Biology from Brandeis University and a J.D. from Northeastern University Law School. We believe that Ms. Greenwood's extensive experience in the pharmaceutical, biotechnology and digital health industries qualifies her to serve on our board of

Travis Whitfill has served as a member of our board of directors since May 2018. Mr. Whitfill has served as a partner at Bios Equity Partners, LP, a biotechnology-focused venture capital firm, since October 2015 and a Senior Analyst at Bios Research since September 2014. He is also the founder and has served in various roles at Azitra Inc., including Chief Scientific Officer from January 2014 to September 2019 and currently serves as the Executive Director of Advanced Technology since September 2019. He has also served as an associate research scientist with appointments in the Departments of Pediatrics and Emergency Medicine at Yale University since July 2016. Mr. Whitfill has led numerous grant-funded projects, holds several patents and has co-authored over 50 publications. Mr. Whitfill received a B.S. from Dallas Baptist University, a MPhil from UCL in the United Kingdom, and an MPH from Yale University. We believe that Mr. Whitfill's strong background in entrepreneurship and in the biotech and healthcare industries qualifies him to serve on our board of directors.

#### **Family Relationships and Other Arrangements**

There are no family relationships among our directors and executive officers. Travis Whitfill was designated as a director to our board of directors by the majority of the holders of preferred stock pursuant to our voting agreement, which will terminate upon the completion of this offering.

# **Board Composition**

Our board of directors currently consists of six members. In accordance with our amended and restated certificate of incorporation, which will be effective immediately after the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Emily T. Fairbairn and Luba Greenwood and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors will be Peter Brandt and Travis Whitfill, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors will be William Ho and Alan S. Roemer, and their terms will expire at the annual meeting of stockholders to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

## **Director Independence**

Under The Nasdaq Stock Market LLC, or Nasdaq, Marketplace Rules, or the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors as a public company within one year of listing.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors, except William Ho, have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements of the Nasdaq Listing Rules. Our board of directors has determined that Mr. Ho, by virtue of his position as our President and Chief Executive Officer, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

# **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which we will post on our website at www.in8bio.com upon the completion of this offering.

# **Audit Committee**

The audit committee is responsible for assisting our board of directors in its oversight of the integrity of our financial statements, the qualifications and independence of our independent auditors and our internal financial and accounting controls. The audit committee has direct responsibility for the

appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the audit committee. The audit committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

Our audit committee consists of Peter Brandt, Luba Greenwood and Alan S. Roemer. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The chair of our audit committee is Peter Brandt. Our board of directors has determined that Peter Brandt is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

## **Compensation Committee**

The compensation committee approves the compensation objectives for the company, the compensation of the chief executive officer and approves, or recommends to our board of directors for approval, the compensation for other executives. The compensation committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

Our compensation committee consists of Luba Greenwood, Alan S. Roemer and Travis Whitfill. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is Alan S. Roemer.

## Nominating and Corporate Governance Committee

The nominating and corporate governance committee makes recommendations regarding corporate governance, the composition of our board of directors, identification, evaluation and nomination of director candidates and the structure and composition of committees of our board of directors. In addition, the nominating and corporate governance committee is responsible for developing and recommending corporate governance guidelines to our board of directors, as applicable to the company.

Our nominating and corporate governance committee consists of Peter Brandt, Emily T. Fairbairn and Travis Whitfill. The chair of our nominating and corporate governance committee is Travis Whitfill. Each member of the nominating and corporate governance committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act, an independent director as defined by the Nasdaq Listing Rules and is free from any relationship that would interfere with the exercise of his or her independent judgment, as determined by the board of directors in accordance with the applicable Nasdaq Listing Rules.

# **Compensation Committee Interlocks and Insider Participation**

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

## **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions, and agents and representatives. The full text of our code of business conduct and ethics will be posted on our website at www.in8bio.com upon the completion of this offering. The nominating and corporate governance committee of our board of directors will be responsible for overseeing our code of business conduct and ethics and any waivers applicable to any director, executive officer or employee. We intend to disclose future amendments

to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and agents and representatives, on our website identified above.

# Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective immediately after the completion of this offering, and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, limits our directors' liability, and may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation
  of law.
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses, including attorneys' fees and disbursements, in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with some of our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

#### **EXECUTIVE AND DIRECTOR COMPENSATION**

Our named executive officers for the year ended December 31, 2020, which consist of our principal executive officer and our two most highly compensated executive officers, are:

- William Ho, our President, Chief Executive Officer and former Chief Financial Officer;
- · Lawrence Lamb, Ph.D., our Executive Vice President and Chief Scientific Officer; and
- Melissa Beelen, our Vice President of Clinical Operations.

# **Summary Compensation Table**

The following table provides information regarding the compensation earned by our named executive officers for the years ended December 31, 2020 and 2019.

Name and Principal Position	Year	Salary (\$) <sup>(1)</sup>	Bonus (\$)	Option Awards (\$) <sup>(3)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(4)</sup>	Total (\$)
William Ho	2020	279,167	150,000 <sup>(2)</sup>	874,540	144,000	1,447,707
President, Chief Executive Officer and former	2019	213,505	_	_	_	213,505
Chief Financial Officer						
Lawrence Lamb, Ph.D.	2020	245,000		1,311,810	120,000	1,676,810
Executive Vice President and Chief Scientific	2019	240,000	_	112,935	_	352,935
Officer						
Melissa Beelen <sup>(5)</sup>	2020	212,333	_	297,725	65,000	570,058
Vice President of Clinical Operations	2019	156,000	_	30,359	41,600	227,659

<sup>(1)</sup> Salary amounts represent actual amounts earned during the applicable year. See "—Narrative to the Summary Compensation Table—Annual Base Salary" below.

- (4) See "—Narrative to Summary Compensation Table—Non-Equity Incentive Plan Compensation" below for a description of the material terms of the program pursuant to which this compensation was awarded."
- (5) Ms. Beelen has resigned as our Vice President of Clinical Operations, effective as of mid-August 2021, due to personal reasons.

# **Narrative to the Summary Compensation Table**

# **Annual Base Salary**

Our named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. During 2020, Dr. Lamb's

<sup>(2)</sup> Amount represents a cash bonus earned by Mr. Ho. See "—Employment Arrangements—William Ho" below.

<sup>(3)</sup> In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during the years presented, computed in accordance with ASC 718 for stockbased compensation transactions. Assumptions used in the calculation of these amounts are included in the notes to our audited financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

base salary was \$240,000 through November 2020 when it was increased to \$300,000, and Ms. Beelen's base salary was \$208,000 through November 2020 when it was increased to \$260,000. During 2020, Mr. Ho's base salary was \$250,000 through November 2020 when it was increased to \$400.000.

### **Equity-Based Incentive Awards**

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees and consultants, including our named executive officers. We have historically used stock options as an incentive for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which exercise price is set at the fair market value of our common stock on the date of grant. We may grant equity awards at such times as our board of directors determines appropriate. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to this offering, all of the stock options we have granted were made pursuant to our 2018 Equity Incentive Plan, as amended, or the 2018 Plan. Following this offering, we will grant equity incentive awards under the terms of our 2020 Equity Incentive Plan, or the 2020 Plan. The terms of our equity plans are described below under "—Equity Incentive Plans."

We have historically awarded stock options with exercise prices that are equal to the fair market value of our common stock on the date of grant as determined by our board of directors. Our stock option awards generally vest over a four-year period, and may be subject to acceleration of vesting and exercisability under certain termination and change in control events. See "—Outstanding Equity Awards at Fiscal Year-End" below for additional information.

# Non-Equity Incentive Plan Compensation

We develop a performance-based bonus program annually. Under the 2020 annual performance bonus program, each named executive officer was eligible to be considered for an annual performance bonus based on (1) the individual's target bonus, as a percentage of base salary, and (2) the percentage attainment of our corporate goals established by our board of directors in its sole discretion and communicated to each officer. Each named executive officer is assigned a target bonus expressed as a percentage of his or her base salary, which for 2020 was 40% for Mr. Ho, 40% for Dr. Lamb and 25% for Ms. Beelen. For 2020, our board of directors determined that our percentage attainment level was 100% for Dr. Lamb and Ms. Beelen and 90% for Mr. Ho. Accordingly, our board of directors approved performance bonuses for each of the named executive officers as reflected in the column of the Summary Compensation Table above entitled "Non-Equity Incentive Plan Compensation."

# **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding the outstanding equity awards held by our named executive officers as of December 31, 2020. All awards were granted pursuant to the 2018 Plan. See "—Equity Incentive Plans—2018 Equity Incentive Plan" below for additional information.

	Option Awards									
Name and Principal Position	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option Exercise Price (\$)	Option Expiration Date				
William Ho	October 5, 2020	_	182,500 <sup>(1)</sup>	_	\$6.74	October 4, 2030				
President, Chief Executive Officer and former Chief Financial Officer										
Lawrence Lamb, Ph.D.	November 12, 2018	48,665	6,085 <sup>(2)</sup>	_	\$1.07	November 11, 2028				
Executive Vice	March 12, 2019	28,216	30,671 <sup>(3)</sup>	(4)	\$1.07	March 11, 2029				
President and Chief Scientific Officer	March 12, 2019 October 5, 2020	_	22,082 <sup>(4)</sup> 273,750 <sup>(5)</sup>	66,248 <sup>(4)</sup>	\$1.07 \$6.74	March 11, 2029 October 4, 2030				
Melissa Beelen	April 17, 2019	16,326	22,858 <sup>(6)</sup>	_	\$1.07	April 16, 2029				
Vice President of	May 5, 2020	_	13,140 <sup>(7)</sup>	(8)	\$1.23	May 4, 2030				
Clinical Operations	May 5, 2020	_	57,434 <sup>(9)</sup>	5,110 <sup>(8)</sup>	\$1.23	May 4, 2030				
	October 5, 2020	_	57,434`		\$6.74	October 4, 2030				

- (1) Of the shares underlying this option, 25% vest on October 5, 2021 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.
- (2) The shares underlying this option vest in 36 equal monthly installments, subject to the executive officer's continuous service.
- (3) Of the shares underlying this option, 25% vested on January 1, 2020 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.
- (4) Of the shares underlying this option, 22,082 options will vest six months after completion of this offering and 66,248 will vest upon achievement of certain milestone events, subject to the executive officer's continuous service.
- (5) Of the shares underlying this option, 25% vest on October 1, 2021 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.
- (6) Of the shares underlying this option, 25% vested on April 1, 2020 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.
- (7) Of the shares underlying this option, 25% vest on May 5, 2021 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.
- (8) The shares underlying this option vest upon the achievement of certain milestone events, subject to the executive officer's continuous service.
- (9) Of the shares underlying this option, 25% vest on October 5, 2021 and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive officer's continuous service.

## **Employment Arrangements**

We have entered into employment agreements and offer letter agreements setting forth the terms and conditions of employment for each of our named executive officers. The material terms of each of these agreements are described below. The employment of each of our named executive officers is "at will" and may be terminated at any time. In addition, each of our named executive officers has executed our standard employee confidential information and invention assignment agreement, which includes, among other things, non-solicitation and non-competition provisions.

# William Ho

In December 2020, we entered into an amended and restated employment agreement with William Ho, our President and Chief Executive Officer. The amended employment agreement reflects Mr. Ho's current annual base salary of \$400,000, which will be increased to \$500,000 following the

completion of this offering, and provides that Mr. Ho's target annual performance bonus is equal to 40% of his annual base salary, which will be increased to 50% following the completion of this offering. In addition, pursuant to the terms of Mr. Ho's prior employment agreement with us, as amended, Mr. Ho received a cash bonus of \$150,000 upon the closing of our Series A financing in August 2020.

If we terminate Mr. Ho's employment with us without cause (as defined in his amended employment agreement), he will receive the following severance payments and benefits if he timely executes and does not revoke a release of claims in our favor and complies with certain restrictive covenants and continuing obligations: (i) continued payments of his then-current annual base salary for 18 months and (ii) accelerated vesting of the then-unvested portion of each of his outstanding time-based equity awards that would have become vested had he remained employed by us for an additional 18 months following his termination.

#### Lawrence Lamb, Ph.D.

In December 2020, we entered into an amended and restated employment agreement with Dr. Lawrence Lamb, our Executive Vice President and Chief Scientific Officer. The amended employment agreement reflects Dr. Lamb's current annual base salary of \$300,000, which will be increased to \$350,000 following the completion of this offering, and provides that Dr. Lamb's target annual performance bonus is equal to 40% of his annual base salary. In connection with the commencement of his employment with us, our board of directors granted Dr. Lamb an option to purchase 147,218 shares of our common stock at a per share exercise price equal to \$1.07 on March 12, 2019.

If we terminate Dr. Lamb's employment with us without cause (as defined in his employment agreement), he will receive continued payments of his then-current annual base salary for nine months and, to the extent Dr. Lamb achieved any of the performance goals for such calendar year, a prorated bonus, subject to his timely execution and non-revocation of a release of claims in our favor and compliance with certain restrictive covenants and continuing obligations.

#### Melissa Beelen

In December 2020, we entered into an amended and restated offer letter agreement with Melissa Beelen, our Vice President, Clinical Operations. The amended offer letter agreement reflects Ms. Beelen's current annual base salary of \$260,000, which will be increased to \$300,000 following the completion of this offering, and provides that Ms. Beelen's target annual performance bonus is equal to 30% of her annual base salary. In connection with the commencement of her employment with us, and pursuant to the terms of her initial offer letter agreement, our board of directors granted Ms. Beelen an option to purchase 39,184 shares of our common stock at a per share exercise price equal to \$1.07 on April 17, 2019. Ms. Beelen has resigned as our Vice President, Clinical Operation, effective mid-August 2021, due to personal reasons.

# Potential Payments and Benefits upon Termination or Change in Control

Mr. Ho's and Dr. Lamb's employment agreements provide for severance benefits as described above under "—Employment Arrangements."

## Health and Welfare and Retirement Benefits; Perquisites

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances.

## 401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. We do not match contributions made by participants to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k)

plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Our board of directors may elect to adopt qualified or nonqualified benefit plans in the future, if it determines that doing so is in our best interests.

## **Equity Benefit Plans**

# 2020 Equity Incentive Plan

Our board of directors has adopted, and prior to the completion of this offering, we expect that our stockholders will approve, our 2020 Plan. We expect our 2020 Plan will become effective on the date of the underwriting agreement related to this offering. Our 2020 Plan will come into existence upon its adoption by our board of directors, but no grants will be made under our 2020 Plan prior to its effectiveness. Once our 2020 Plan becomes effective, no further grants will be made under our Prior Plan.

Awards. Our 2020 Plan will provide for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2020 Plan after it becomes effective will not exceed shares of our common stock, which is the sum of (i) new shares, plus (ii) an additional number of shares consisting of shares subject to outstanding stock options or other stock awards granted under our Prior Plan that, on or after our 2020 Plan becomes effective, terminate or expire prior to exercise or settlement: are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under our 2020 Plan 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 (1) 5% of the total number of shares of our common stock outstanding on the last day of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than the last day of the immediately preceding year. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2020 Plan will be shares.

Shares subject to stock awards granted under our 2020 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2020 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2020 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2020 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2020 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2020 Plan, our board of directors will have the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2020 Plan, our board of directors also generally will have the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or

strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator will determine the exercise price for stock options, within the terms and conditions of our 2020 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2020 Plan will vest at the rate specified in the stock option agreement as will be determined by the administrator.

The administrator will determine the term of stock options granted under our 2020 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration

for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator will determine the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under our 2020 Plan will vest at the rate specified in the stock appreciation right agreement as will be determined by the administrator. Stock appreciation rights may be settled in cash or shares of our common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator will determine the term of stock appreciation rights granted under our 2020 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2020 Plan will permit the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles: (iv) to exclude the effects of any statutory adjustments to corporate tax rates: (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split. stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The administrator will be permitted to grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed \$700,000 in total value, except such amount will increase to \$1,000,000 for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2020 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of a corporate transaction (as defined below), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2020 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our common stock.

Under our 2020 Plan, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Stock awards granted under our 2020 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in

the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under our 2020 Plan, a "change in control" is generally (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) stockholder approval of a complete dissolution or liquidation; (iv) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (v) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2020 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2020 Plan. No stock awards may be granted under our 2020 Plan while it is suspended or after it is terminated.

#### 2020 Employee Stock Purchase Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our ESPP. Our ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of our ESPP will be to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

Share Reserve. Following this offering, our ESPP will authorize the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance 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, 2030, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the immediately preceding year; and (ii) 420,000 shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

Administration. Our board of directors will administer our ESPP and may delegate its authority to administer our ESPP to our compensation committee. Our ESPP will be implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under our ESPP, our board of directors will be permitted to specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. Our ESPP will provide that an offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, will be eligible to participate in our ESPP and to contribute, normally through payroll deductions, up to 15% of their earnings (as defined in our ESPP) for the

purchase of our common stock under our ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in our ESPP at a price per share that is at least equal to the lesser of (i) 85% of the fair market value of a share of our common stock on the first day of an offering, or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations*. Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee will be permitted to purchase shares under our ESPP at a rate in excess of \$25,000 worth of our common stock (based on the fair market value per share of our common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. Our ESPP will provide that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. Our ESPP will provide that in the event of a corporate transaction (as defined below), any then-outstanding rights to purchase our stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under our ESPP, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Amendment or Termination. Our board of directors will have the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

### 2018 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, our Prior Plan on May 7, 2018. Our Prior Plan was most recently amended on August 21, 2020. No further stock awards will be granted under our Prior Plan on or after the effectiveness of our 2020 Plan; however, awards outstanding under our Prior Plan will continue to be governed by their existing terms.

*Stock Awards*. Our Prior Plan provides for the grant of ISOs to our employees and our parent and subsidiary corporations' employees, and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other forms of stock awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

*Authorized Shares.* As of December 31, 2020, we had reserved 2,101,478 shares of our common stock for issuance under our Prior Plan. As of December 31, 2020, 1,247,158 stock options to purchase shares of our common stock remained outstanding under our Prior Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, administers our Prior Plan. The administrator has the authority to construe and interpret our Prior Plan and stock awards granted under our Prior Plan and to make all other determinations necessary or expedient for the administration of our Prior Plan. Under our Prior Plan, the administrator also has the authority to effect, with the consent of any adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding stock award; (ii) the cancellation of any outstanding stock award and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. Stock options granted under our Prior Plan are subject to terms similar to those described above with respect to stock options that may be granted under our 2020 Plan on and after it becomes effective.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class(es) and maximum number of shares reserved for issuance under our Prior Plan, (ii) the class(es) and maximum number of shares that may be issued on the exercise of ISOs and (iii) the class(es) and number of shares and price per share, if applicable, of stock subject to outstanding stock awards.

Corporate Transaction. Our Prior Plan provides that in the event of a corporate transaction (as defined below), unless otherwise provided in an award agreement or other written agreement between us and the participant, our board of directors may take one or more of the following actions with respect to outstanding stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by the surviving or acquiring corporation or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring corporation or parent company;
- accelerate the vesting, in whole or in part, of the stock award and, if applicable, the time at
  which the stock award may be exercised, to a date prior to the effective time of the corporate
  transaction and provide for its termination if not exercised (if applicable) at or prior to the
  effective time of the corporate transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel the stock award, to the extent not vested or not exercised prior to the effective time of the corporate transaction, in exchange for such cash consideration, if any, as our board of directors deems appropriate; and
- make a payment, in such form as determined by our board of directors, equal to the excess, if
  any, of the value of the property the participant would have received upon the exercise of the
  stock award immediately prior to the effective time of the corporate transaction over any
  exercise price payable by the holder in connection with such exercise.

Our board of directors is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to treat all participants in the same manner.

Under our Prior Plan, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of more than 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction

Change in Control. A stock award under our Prior Plan may be subject to additional acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in the award agreement or any other written agreement between us and the participant, but in the

absence of such provision, no such acceleration will occur. Under our Prior Plan, a "change in control" is generally (i) the acquisition by any person or entity of more than 50% of the combined voting power of our then outstanding securities other than by merger, consolidation, or similar transaction; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; or (iii) a sale, lease, exclusive license or other disposition of all or substantially all of our consolidated assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction.

Plan Amendment and Termination. Our board of directors may amend, suspend, or terminate our Prior Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments of our Prior Plan also require the approval of our stockholders. As noted above, no further awards will be granted under our Prior Plan on or after the effectiveness of our 2020 Plan; however, awards outstanding under our Prior Plan will continue to be governed by their existing terms.

#### **Non-Employee Director Compensation**

We have not historically had a formal compensation policy with respect to service on our board of directors, but we have reimbursed our non-employee directors for direct expenses incurred in connection with attending meetings of our board of directors or its committees, and occasionally granted stock options.

In November 2020, our board of directors approved a non-employee director compensation policy that will be effective upon the effectiveness of the registration statement of which this prospectus is a part. This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders. Under this policy, we will pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairperson of each committee will receive a higher retainer for such service. These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors or the applicable committee. The retainers to be paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

Position	Annual Service Retainer	Additional Retainer
Board of Directors	\$35,000	\$65,000
Audit Committee	7,500	15,000
Compensation Committee	5,000	10,000
Nominating and Corporate Governance Committee	4,000	8,000

In addition, under our non-employee director compensation policy, each non-employee director elected to our board of directors after the completion of this offering will receive an option to purchase 21,000 shares of our common stock. The shares subject to this initial option grant will vest monthly over a three-year period, subject to the director's continued service as a director. Further, on the date of each annual meeting of stockholders held after the completion of this offering, each non-employee director that continues to serve as a non-employee director will receive an option to purchase 10,500 shares of our common stock. The shares subject to each annual option grant will vest in equal monthly installments over the 12 months following the date of grant and, notwithstanding the foregoing, will be fully vested on the date of Company's next annual stockholder meeting, subject to the director's continued service as a director. The exercise price per share of these options will equal the fair market value of our common stock on the date of grant. All options granted under this policy will vest in full upon the occurrence of a change in control (as defined in the 2020 Plan) prior to the termination of the director's continuous service.

#### 2020 Director Compensation Table

The following table sets forth information regarding the compensation earned for service on our board of directors by our non-employee directors during the year ended December 31, 2020. Other than as set forth below for Mr. Roemer, no directors received any cash compensation for their service on our board of directors during 2020. Mr. Ho is a member of our board of directors, but he did not receive any additional compensation for service as a director. Mr. Ho's compensation as a named executive officer is set forth above under "—Summary Compensation Table."

Name	Fees Earned or Paid in Cash (\$)	Option Awards <sup>(1)(4)</sup> (\$)	Total (\$)
Traine - I	(Ψ)	(Ψ)	
Peter Brandt	<del>-</del>	203,848	203,848
Thomas Cirrito, Ph.D. <sup>(5)</sup>	_	218,544	218,544
Alan S. Roemer	30,769 <sup>(2</sup>	) 1,081,960 <sup>(3)</sup>	1,112,729
Travis Whitfill	_	10,815	10,815

- (1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during fiscal year 2020 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in the notes to our audited financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.
- (2) Amount represents the annual compensation of \$100,000 earned by Mr. Roemer as Chairman of the board of directors, prorated for the portion of the year during which Mr. Roemer served in such position.
- (3) Reflects an option to purchase 225,879 shares of our common stock, which Mr. Roemer received upon his appointment to our board of directors in September 2020.
- (4) The following table provides information regarding the number of shares of common stock underlying stock options granted to our non-employee directors that were outstanding as of December 31, 2020:

Name	Outstanding Option 
Peter Brandt	72,221
Thomas Cirrito, Ph.D.	76,650
Travis Whitfill	12,775
Alan S. Roemer	225.879

(5) Effective July 19, 2021, Dr. Cirrito is no longer a member of our board of directors.

#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this prospectus, the following includes a summary of transactions since January 1, 2018 and any currently proposed transactions, to which we were or are to be a participant, in which

- the amount involved exceeded or will exceed the lesser of (1) \$120,000 or (2) 1% of the
  average of our total assets for the last two completed fiscal years, and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

## **Corporate Reorganization**

We were incorporated under the laws of the State of Delaware on May 7, 2018. We were formed by the domestication of Incysus, Ltd., a Bermuda entity formed in February 2016, into the State of Delaware under the name Incysus Therapeutics, Inc. In August 2020, we amended our charter to change our name to IN8bio, Inc. Upon completion of the domestication, all outstanding Class A shares of Incysus, Ltd., including Class A shares held by certain of our directors and executive officers, were automatically converted into an equivalent amount of shares of our common stock and each Class B share of Incysus, Ltd. was automatically cancelled and did not convert into any shares of any class of our capital stock.

#### **Promissory Note with Our Executive Officer**

In August 2017, we issued a promissory note to our President and Chief Executive Officer, William Ho, which entitled us to borrow up to \$100,000 through December 31, 2017. We entered into an amendment to the promissory note in March 2018, which permitted us to borrow up to an aggregate of \$150,000 through April 30, 2018, with any amounts outstanding to be repaid on April 30, 2018. All amounts outstanding under the promissory note accrued interest at a rate of 5% per annum. We repaid the then-outstanding balance of \$122,730 on May 9, 2018, which included \$2,730 in accrued interest.

## **Preferred Stock, Warrant and Convertible Note Financings**

## Convertible Note Financing

In April 2018, our predecessor entity issued an aggregate principal amount of \$2.5 million of convertible notes, or the 2018A Notes, shortly prior to our domestication to a Delaware corporation. See "—Corporate Reorganization" above. The 2018A Notes accrued interest at a rate equal to the annual short-term Applicable Federal Rate as published by the U.S. Internal Revenue Service for the month in which the 2018A Notes were outstanding. In May 2018, we closed on a portion of the Series A preferred stock financing described below in connection with our domestication, at which time all 2018A Notes and the then-accrued interest totaling \$2.5 million were converted into 694,212 shares of our Series A preferred stock.

## Series A Preferred Stock Financing and Warrants

Between May 2018 and August 2020, we issued an aggregate of 9,762,331 shares of our Series A preferred stock at an original price per share of \$3.58330 for total gross proceeds of \$32.5 million, excluding proceeds from the sale of the 2018A Notes.

Concurrently with the conversion of the 2018A Notes, we sold an additional 627,927 shares of our Series A preferred stock in the initial closing of our Series A preferred stock financing on May 7, 2018, or the initial closing. In connection with the initial closing of the Series A preferred stock financing, certain Series A investors, including entities affiliated with Bios Partners and entities affiliated with Emily T. Fairbairn, were issued five-year warrants, or the Series A warrants, entitling such individuals to purchase up to an aggregate of 231,396 shares of our Series A preferred stock at an exercise price of \$0.0003 per share. In October 2020, certain of these individuals, including entities affiliated with Bios Equity Partners, L.P. and entities affiliated with Emily T. Fairbairn, exercised their respective Series A warrants for an aggregate of 231,396 shares of Series A preferred stock, for aggregate proceeds to us of \$64.

See the section titled "Description of Capital Stock—Series A Warrants" elsewhere in this prospectus for more information on the Series A warrants.

Between May and July 2018, we issued an aggregate of 1,712,250 shares of our Series A preferred stock for aggregate gross proceeds of \$6.1 million (excluding the shares issued upon the conversion of the 2018A Notes). In August 2018, we issued an additional 52,810 shares of our Series A preferred stock for aggregate gross proceeds of \$0.2 million. Between October and December 2018, we issued an additional 539,877 shares of our Series A preferred stock for aggregate gross proceeds of \$0.9 million.

Between January and February 2020, we issued an additional 1,533,947 shares of our Series A preferred stock for aggregate gross proceeds of \$5.5 million. In August 2020, we issued an additional 5,514,404 shares of our Series A preferred stock for aggregate gross proceeds of \$19.8 million.

The table below sets forth the aggregate number of shares of our Series A preferred stock and warrants purchased by the holders of more than 5% of our capital stock and affiliates, including shares issued upon conversion of the 2018A Notes purchased by such investors. Each share of Series A preferred stock in the table below will automatically convert into 1.09970 shares of our common stock upon the completion of this offering. For a description of the material rights and privileges of the Series A preferred stock, see Note 6 to our financial statements included elsewhere in this prospectus.

Name	Series A Preferred Stock (#)	Warrants to Purchase Series A Preferred Stock (#) <sup>(3)</sup>	Cancellation of Indebtedness (2018 Note Conversion(\$)	Cash Purchase Price of Series A Preferred Stock (\$)	Aggregate Purchase Price (\$)
Entities affiliated with Bios Equity Partners, L.P. <sup>(1)</sup>	5,861,427	163,049	1,752,744	19,250,000	21,002,744
Entities affiliated with Emily T. Fairbairn <sup>(2)</sup>	3,005,920	25,195	270,850	10,500,000	10,770,850

<sup>(1)</sup> Travis Whitfill, a member of our board of directors, is a partner at Bios Equity Partners, L.P.

## **Common Stock Issuance**

In March 2020, we entered into a common stock purchase agreement with Peter Brandt, a member of our board of directors, to issue and sell 182,500 shares of our common stock for a total purchase price of \$0.2 million.

In October 2020, we entered into a common stock purchase agreement with Alan S. Roemer, a member of our board of directors, to issue and sell 29,674 shares of our common stock for a total purchase price of \$0.2 million.

## **Settlement Agreement**

In July 2020, we entered into a settlement agreement with a former employee, pursuant to which we paid \$0.3 million in cash and issued 200,750 shares of our common stock.

# **Director Antidilution Rights**

In connection with Peter Brandt's appointment to our board of directors in 2019, he was granted the right to receive an option to purchase shares of our common stock, at an exercise price equal to the fair market value of the shares on the date of grant, that, combined with his outstanding stock options, represented 0.5% of our fully diluted capitalization (excluding shares issuable upon exercise of warrants or under our equity incentive plans) upon the closing of a sale of our capital stock generating gross proceeds to us of at least \$25.0 million, or a Qualified Financing. Upon the closing of the Series A preferred stock financing in August 2020, Mr. Brandt was entitled to receive an option to

<sup>(2)</sup> Emily T. Fairbairn is the sole managing member of Transcend Partners Opportunity Fund LLC, the sole managing partner of Valley High Limited Partnership and exercises control over the Emily T. Fairbairn Roth IRA.

<sup>(3)</sup> These warrants were exercised in full in October 2020.

purchase 42,557 shares of our common stock. This option was granted to Mr. Brandt on October 5, 2020 at a price per share of \$6.74, which satisfied Mr. Brandt's antidilution rights in full.

In connection with Alan S. Roemer's appointment to our board of directors in 2020, he was granted the right to receive an option to purchase shares of our common stock, at an exercise price equal to the fair market value of the shares on the date of grant, that, combined with his existing stock option grant, represents 1.5% of our fully diluted capitalization (including shares issuable upon exercise of warrants or warrants or reserved for issuance under our equity incentive plans) upon the closing of a Qualified Financing. Upon the completion of this offering and in satisfaction of the antidilution right, Mr. Roemer will receive an option to purchase shares of our common stock, assuming the sale in this offering of the number of shares set forth on the cover page of this prospectus at the assumed public offering price of per share, which is the midpoint of the price range set forth on the cover page of this prospectus. The final number of shares subject to such option will be determined in connection with the pricing of this offering.

#### **Investors' Rights Agreement**

We are party to an investors' rights agreement, or the Rights Agreement, dated May 7, 2018, with the holders of our Series A preferred stock, including all holders of more than 5% of our capital stock, as well as with William Ho and Peter Brandt. The Rights Agreement provides that these holders are entitled to certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we otherwise file. In addition to the registration rights, the Rights Agreement provides for certain information rights and rights of first offer in favor of certain holders of our outstanding preferred stock with regard to certain issuances of our capital stock. The information rights and rights of first offer will terminate immediately prior to the consummation of this offering. The registration rights will terminate upon the earliest of (i) the closing of a deemed liquidation event, (ii) with respect to each stockholder, the date when such stockholder can sell all of its registrable shares without limitation during a three-month period without registration pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act and (iii) three years after the completion this offering. For a detailed description of the registration rights, see the section titled "Description of Capital Stock—Registration Rights."

## **Indemnification Agreements**

We have entered or intend to enter, and intend to continue to enter, into separate indemnification agreements with some of our directors and executive officers, in addition to the indemnification provided for in our bylaws. These indemnification agreements provide our directors and executive officers with contractual rights to indemnification and, in some cases, expense advancement in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. For more information regarding these indemnification agreements, see the section titled "Management—Limitation on Liability and Indemnification Matters."

#### **Related Party Transaction Policy**

Prior to the completion of this offering, we intend to adopt a policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. For purposes of this policy only, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are participants involving an amount that exceeds or will exceed the lesser of (1) \$120,000 or (2) 1% of the average of our total assets for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A "related person" is any executive officer, director, nominee to become a director or a holder of more than 5% of our capital stock, or any member of the immediate family of the foregoing.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee or, where review by our audit committee would be inappropriate due to a conflict of interest, to

another independent body of our board of directors, for review. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. All of the transactions described in this section were entered into prior to the adoption of this policy.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of June 30, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors:
- · each of our named executive officers; and
- all of our current executive officers and directors as a group.

The percentage ownership information under the column titled "Before Offering" is based on 14,754,553 shares of common stock outstanding as of June 30, 2021, assuming the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 10,990,065 shares of common stock upon the completion of this offering. The information relating to the number and percentage of shares beneficially owned under the column titled "After Offering" is based on the sale of shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters' option to purchase additional shares to cover over-allotments.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our capital stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable within 60 days of June 30, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them. Except as otherwise noted below, the address for each person or entity listed in the table is c/o IN8bio, Inc., 79 Madison Avenue, New York, New York 10016.

	Number of Shares	Percentage of Shares Beneficially Owned	
	Beneficially Owned	Before Offering	After Offering
Greater than 5% Stockholders:			
Entities affiliated with Bios Equity Partners, L.P. <sup>(1)</sup>	6,625,102	44.9%	
Transcend Partners Opportunity Fund LLC <sup>(2)</sup>	3,222,485	21.8%	
Directors and Named Executive Officers:			
William Ho <sup>(3)</sup>	2,544,929	17.2%	
Lawrence Lamb, Ph.D. <sup>(4)</sup>	186,637	1.3%	
Melissa Beelen <sup>(5)</sup>	26,689	*	
Peter Brandt <sup>(6)</sup>	207,971	1.4%	
Alan S. Roemer <sup>(7)</sup>	86,143	*	
Emily T. Fairbairn <sup>(8)</sup>	3,341,527	22.6%	
Luba Greenwood	7,300	*	
Travis Whitfill <sup>(9)</sup>	12,775	*	
All current executive officers and directors as a group (10 persons)			
(10)	6,511,152	43.3%	

- \* Represents beneficial ownership of less than 1%.
- (1) Includes (a) 251,211 shares issuable upon the conversion of Series A preferred stock held by Bios Fund II NT, LP ("Fund II NT"), (b) 1,876,624 shares issuable upon the conversion of Series A preferred stock held by Bios Fund II QP, LP ("Fund II QP"), (c) 574,432 shares issuable upon the conversion of Series A preferred stock held by Bios Fund II, L.P. ("Bios Fund II"), (d) 340,712 shares issuable upon the conversion of Series A preferred stock held by Bios Fund III, L.P. ("Fund III"), (e) 359,374 shares issuable upon the conversion of Series A preferred stock held by Bios Fund III NT, L.P. ("Fund III NT"), (f) 2,225,316 shares issuable upon the conversion of Series A preferred stock held by Bios Fund III QP, L.P. ("Fund III QP"), and (g) 997,433 shares held by Bios Incysus Co-Invest I, LP. Bios Equity Partners II, LP ("Equity II") is the general partner of Fund II NT, Fund II QP, Bios Fund II and Co-Invest. Bios Equity Partners III, LP ("Equity III") is the general partner of Fund, III NT, Fund III QP and Fund III. Cavu Management, LP and Bios Capital Management, LP are the general partners of Equity II and Equity III. Cavu Advisors LLC ("Cavu Advisors") is the general partner of Cavu Management LP. Bios Advisors GP, LLC ("Bio Advisors") is the general partner of Bios Capital Management, LP. Leslie Kreis, Jr. is a managing partner of Equity II, Equity III, and a manager of Cavu Advisors. Aaron Fletcher is a managing partner of Equity II, Equity III, and a manager of Bios Advisors. Mr. Kreis and Mr. Fletcher have shared voting and investment power over the shares described in this footnote 1. Travis Whitfill, a director of the Company, is a partner at Bios Equity Partners, LP. but does not have voting or investment power over the shares described in this footnote 1. The address of Bios Equity Partners, LP is 1751 River Run, Suite 400, Fort Worth, Texas 76107.
- (2) Emily T. Fairbairn is the sole managing member of Transcend Partners Opportunity Fund LLC ("Transcend"), and as such, has voting and investment power over the shares held by Transcend. The address of Transcend is 10 Orinda View Road, Orinda, CA 94563.
- (3) Includes (a) 182,499 shares held by Mr. Ho's children and (b) 73,000 shares held by other relatives of Mr. Ho over which Mr. Ho has voting power pursuant to a voting proxy.
- (4) Includes 113,637 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021.
- (5) Consists of 26,689 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021.
- (6) Includes (a) 182,500 shares held by The Peter C. Brandt 2020-4 GRAT (the "GRAT") and (b) 25,471 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021. Mr. Brandt is the trustee of the GRAT and, as such, has voting and investment power over the shares held by the GRAT.
- (7) Includes of 56,469 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021.
- (8) Consists of (a) the shares described in footnote 2, (b) 27,706 shares issuable upon the conversion of Series A preferred stock held by Emily T. Fairbairn ("Roth IRA") and (c) 8,212 shares and 83,124 shares issuable upon the conversion of Series A preferred stock held by Valley High Limited Partnership ("Valley High"). Emily T. Fairbairn is the sole managing member of Transcend and the sole managing partner of Valley High, and exercises control over the Roth IRA, and as such, has voting and investment power over the shares held by Transcend, Valley High and Roth IRA.
- (9) Consists of 12,775 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021.
- (10) Includes 277,472 shares underlying outstanding options that are immediately exercisable or will be immediately exercisable within 60 days of June 30, 2021.

#### **DESCRIPTION OF CAPITAL STOCK**

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation, the amended and restated bylaws and the amended and restated investors' rights agreement, which are filed as exhibits to the registration statement of which this prospectus is a part.

#### General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 490,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share.

#### **Common Stock**

#### **Outstanding Shares**

As of March 31, 2021, we had 14,754,553 shares of common stock outstanding, which assumes the automatic conversion of all of our outstanding shares of preferred stock into 10,990,065 shares of common stock upon the completion of this offering. Our common stock was held by 25 stockholders of record as of March 31, 2021.

## Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66\(^2\)3\% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

#### **Dividends**

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

# Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

## **Rights and Preferences**

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

# **Preferred Stock**

We will not have any preferred shares outstanding following the completion of this offering. Immediately after the completion of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or

restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Stock Options**

As of March 31, 2021, 1,552,290 shares of common stock were issuable upon the exercise of outstanding stock options under the 2018 Plan, at a weighted-average exercise price of \$5.16 per share. For additional information regarding terms of our equity incentive plans, see the section titled "Executive and Director Compensation—Equity Incentive Plans."

#### **Series A Warrants**

In connection with the Series A preferred stock financing in May 2018, we issued Series A warrants to certain investors to purchase an aggregate of 231,396 shares of our Series A preferred stock at an exercise price of \$0.0003 per share. In October 2020, the Series A warrants were exercised and 231,396 shares of Series A preferred stock were issued to such investors.

## **Registration Rights**

Upon the completion of this offering, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the completion of this offering, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144, or other similar exemption, of the Securities Act during any three-month period.

## **Demand Registration Rights**

Upon the completion of this offering, holders of 13,684,805 shares of our common stock, including all shares of common stock issuable upon conversion of outstanding Preferred Stock, will be entitled to certain demand registration rights. At any time beginning on the earlier of the fifth anniversary of the date of our investors' rights agreement or 180 days following the effectiveness of this registration statement, the holders of a majority of registrable securities may request that we register all or a portion of their shares, subject to certain specified exceptions.

## Piggyback Registration Rights

In connection with this offering, holders of 13,684,805 shares of our common stock, including all shares of common stock issuable upon conversion of outstanding preferred stock are entitled to rights to notice of this offering and to include their shares of registrable securities in this offering, which the requisite percentage of holders have waived. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other

security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

## S-3 Registration Rights

Upon the completion of this offering, the holders of 13,684,805 shares of our common stock, including all shares of common stock issuable upon conversion of outstanding preferred stock will initially be entitled to certain Form S-3 registration rights. The holders of at least 25% of registrable securities may, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds \$1.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

#### **Anti-takeover provisions**

### Certificate of Incorporation and Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any
  rights, preferences and privileges as they may designate, including the right to approve an
  acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66%% of the voting power of all of our thenoutstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice:
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66%% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it

possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

## Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

## **Choice of Forum**

Our amended and restated certificate of incorporation to be effective on the completion of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if, the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if, all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action brought under Delaware statutory or common law: (1) any derivative claim or action brought on our behalf; (2) any claim or cause of action asserting a breach of fiduciary duty by any of our current or former director, officer or other employee; (3) any claim or cause of action asserting a claim against us arising out of, or pursuant to, the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (4) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (5) any claim or cause of action as to which the DGCL confers iurisdiction to the Court of Chancery of the State of Delaware; or (6) any claim or cause of action asserting a claim against us or any of our directors, officers or other employees, that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. The aforementioned provision will not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation will further provide that, unless we consent writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum, to the fullest extent permitted by law, 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. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable.

## Limitations of Liability and Indemnification

See the section titled "Executive and Director Compensation—Limitations on Liability and Indemnification Matters."

## Listing

Our common stock is currently not listed on any securities exchange. Our common stock has been approved for listing on The Nasdaq Global Market under the trading symbol "INAB."

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Canton, Massachusetts 02021.

#### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares outstanding as of March 31, 2021, upon the completion of this offering, a total of shares of common stock will be outstanding. Of these shares, all of the common stock sold in this offering by us will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of common stock, including the 1,552,290 shares of common stock subject to stock options outstanding as of December 31, 2020, will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, or Rule 701, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S under the Securities Act.

Subject to the lock-up agreements described below and in the section titled "Underwriting," and the provisions of Rule 144, Rule 701 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

#### **Rule 144**

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below, subject, in the case of restricted securities, to such shares having been beneficially owned for at least six months. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of our common stock then outstanding, which will equal approximately shares of common stock immediately upon the completion of this offering; or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

#### **Rule 701**

Rule 701 generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

#### **Lock-up Agreements**

In connection with this offering, we, our officers and directors, and holders of substantially all of our outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock outstanding upon the completion of this offering, have agreed with the underwriters, subject to certain exceptions, not to directly or indirectly offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date that is 180 days after the date of this prospectus, except with the prior written consent of the representative, and certain other exceptions. These agreements are further described in the section titled "Underwriting."

Following the expiration of the lock-up agreements and assuming that no parties are released from the lock-up agreements, all shares of our common stock that are restricted securities or held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144.

In addition to the restrictions contained in these lock-up agreements, we have entered into agreements with certain security holders, including the investors' rights agreement and our standard form of option agreement, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

# **Registration Rights**

Upon the completion of this offering, the holders of 13,684,805 shares of our common stock, including all shares of common stock issued on conversion of our preferred stock, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above and in the section titled "Underwriting" herein. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock—Registration Rights."

# Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock to be issued under our 2018 Plan, 2020 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

## Rule 10b5-1 Plans

Certain of our employees, executive officers and directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements described above.

#### MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a discussion of the material U.S. federal income tax consequences applicable to non-U.S. holders (as defined below) with respect to their purchase, ownership and disposition of shares of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. All prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock, as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not a U.S. holder. A U.S. holder is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and
  one or more U.S. persons have the authority to control all of the trust's substantial decisions or
  (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be
  treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative rulings and judicial decisions, all as in effect as of the date of this prospectus supplement. These laws are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus supplement.

This discussion is limited to non-U.S. holders that hold shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address the effect of the alternative minimum tax or Medicare contribution tax or the impact of special tax accounting rules under Section 451(b) of the Code, any aspects of U.S. estate or gift tax, or any state, local or non-U.S. taxes. This discussion also does not address all special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, "qualified foreign pension funds" as defined in Section 897(I)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds, controlled foreign corporations, passive foreign investment companies and certain former citizens or long-term residents of the United States.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold our common stock through such partnerships or such entities or arrangements. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and certain

determinations made at the partner level. Such partners and partnerships should consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that the U.S. Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences with respect to the matters discussed below.

#### **Distributions on Our Common Stock**

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock."

Subject to the discussions below regarding effectively connected income, dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy relevant certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification requirements. To claim the exemption, the non-U.S. holder must furnish to us or the applicable withholding agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same U.S. federal income tax rates applicable to a "United States person" (as defined in the Code), which we refer to as a United States person, unless a specific treaty exemption applies. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

## Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the U.S. federal income tax rates applicable to United States persons and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" may also apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met,

- in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Even if we are or become a U.S. real property holding corporation, provided that our common stock is "regularly traded" (as defined by U.S. Treasury Regulations) on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the U.S. federal income tax rates applicable to United States persons. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

## **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of distributions on our common stock paid to such holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a United States person in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. U.S. backup withholding generally will not apply to a non-U.S. holder who provides a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) or otherwise establishes an exemption.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

#### **Foreign Accounts**

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) generally impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as

specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which may include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. FATCA also generally imposes a 30% withholding tax on certain payments made to a non-financial foreign entity, unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or information regarding substantial direct and indirect U.S. owners of the entity. The withholding tax under FATCA described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. The FATCA withholding provisions described above currently apply to dividends on our common stock. The FATCA withholding provisions also would apply to the gross proceeds of a disposition of our common stock, except that the U.S. Treasury Department has released proposed regulations which, if finalized in their present form, would eliminate such withholding. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers generally may rely on the proposed regulations until final regulations are issued.

Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Non-U.S. holders are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

#### **UNDERWRITING**

B. Riley Securities, Inc. is acting as representative of the several underwriters in this offering. Under the terms of an underwriting agreement, which will be filed as an exhibit to the registration statement, with respect to the shares being offered, each of the underwriters named below has severally agreed to purchase from us the respective number of shares of common stock shown opposite its name below:

Underwriters	Number of Shares
B. Riley Securities, Inc.	
Total	

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock depends on the satisfaction of the certain conditions contained in the underwriting agreement including:

- the obligation to purchase all of the shares of common stock offered hereby (other than those shares of common stock covered by their option to purchase additional shares as described below), if any of the shares are purchased;
- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

#### **Commissions and Expenses**

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

The representative has advised us that the underwriters propose to offer the shares of common stock directly to the public at the offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$ per share. If all the shares are not sold at the initial offering price following the initial offering, the representative may change the offering price and other selling terms.

The expenses of the offering that are payable by us are estimated to be approximately \$ (excluding underwriting discounts and commissions). We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$

#### **Option to Purchase Additional Shares**

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the offering price less underwriting discounts and commissions, to cover overallotments, if any. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in this offering as indicated in the above table.

# **Lock-Up Agreements**

We, all of our directors and executive officers, and holders of substantially all of our outstanding stock have agreed that, for a period of 180 days after the date of this prospectus subject to certain limited exceptions, we and they will not directly or indirectly, without the prior written consent of the

representative (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock (other than the stock and shares issued pursuant to employee benefit plans, qualified stock option plans, or other employee compensation plans existing on the date of this prospectus or pursuant to currently outstanding options, warrants or rights not issued under one of these plans), or sell or grant options, rights or warrants with respect to any shares of common stock or securities convertible into or exchangeable for common stock (other than the grant of options pursuant to option plans existing on the date of this prospectus), (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (3) make any demand for or exercise any right or confidentially submit or file or cause a registration statement to be filed or confidentially submitted, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible, exercisable or exchangeable into common stock or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing.

The representative, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release common stock and other securities from lock-up agreements, the representative will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time. At least three business days before the effectiveness of any release or waiver of any of the restrictions with respect to an officer or director of the Company, the representative will notify us of the impending release or waiver and we have agreed to announce the impending release or waiver in accordance with any method permitted by applicable law or regulation (which may include a press release), except where the release or waiver is effected solely to permit a transfer of common stock that is not for consideration and where the transferee has agreed in writing to be bound by the same terms as the lock-up agreements described above to the extent and for the duration that such terms remain in effect at the time of transfer.

## Offering Price Determination

Prior to this offering, there has been no public market for our common stock. The initial offering price was negotiated between the representative and us. In determining the initial offering price of our common stock, the representative considered:

- the history and prospects for the industry in which we compete;
- our financial information;
- · the ability of our management and our business potential and earning prospects;
- the prevailing securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

### Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

# Stabilization, Short Positions and Penalty Bids

The representative may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq Global Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

### **Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representative on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

# Listing on the Nasdaq Global Market

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "INAB."

#### **Stamp Taxes**

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

## Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, certain of those underwriters or their affiliates routinely hedge, and certain other of those underwriters or their affiliates may hedge, their credit exposure to us consistent with their customary risk management policies. Typically, the underwriters and their affiliates would hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the shares of common stock offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the shares of common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

## **Selling Restrictions**

#### General

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### European Economic Area

In relation to each Member State of the European Economic Area, each an EEA State, no shares have been offered or will be offered pursuant to the offering to the public in that EEA State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that EEA State or, where appropriate, approved in another EEA State and notified to the competent authority in that EEA State, all in accordance with the EU Prospectus Regulation, except that it may make an offer to the public in that EEA State of any shares at any time under the following exemptions under the EU Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the EU Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the EU Prospectus Regulation), subject to obtaining the prior consent of underwriters for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the EU Prospectus Regulation, provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the EU Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the EU Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any EEA State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "EU Prospectus Regulation" means Regulation (EU) 2017/1129.

## **United Kingdom**

In relation to the United Kingdom, no shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in accordance with the UK Prospectus Regulation, except that it may make an offer to the public in the United Kingdom of any shares at any time under the following exemptions under the UK Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the UK Prospectus Regulation, provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

In the United Kingdom, the offering is only addressed to, and is directed only at, "qualified investors" within the meaning of Article 2(e) of the UK Prospectus Regulation, who are also (i) persons having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order; (ii) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Order; or (iii) persons to whom it may otherwise lawfully be communicated (all such persons being referred to as "relevant persons"). This document must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offering and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "UK Prospectus Regulation" means the UK version of Regulation (EU) No 2017/1129 as amended by The Prospectus (Amendment etc.) (EU Exit) Regulations 2019, which is part of UK law by virtue of the European Union (Withdrawal) Act 2018.

## Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The

purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

#### Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA") (ii) to a relevant person S-23 pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the or under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets),

(3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

#### Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX"), or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under Article 652a or Article 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under Article 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the "FIEL") has been made or will be made with respect to the solicitation of the application for the acquisition of the shares.

Accordingly, the shares have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

#### Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, which we refer to as Exempt Investors, who are "sophisticated investors" (within the meaning of Section 708(8) of the Corporations Act), "professional investors" (within the meaning of Section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in Section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under Section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any

securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances and, if necessary, seek expert advice on those matters.

#### Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the securities offered hereby is directed only at, (i) a limited number of persons in accordance with the Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

#### **LEGAL MATTERS**

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York. As of the date of this prospectus, partners of Cooley LLP and GC&H Investments, LLC, an entity that is comprised of partners and associates of Cooley LLP, beneficially own an aggregate of 158,171 shares of our Series A preferred stock, which shares of Series A preferred stock will be converted into 173,937 shares of our common stock upon the completion of this offering.

#### **EXPERTS**

Our financial statements as of December 31, 2019 and 2020, and for the years then ended, appearing in this prospectus and registration statement have been audited by CohnReznick LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review on the web site of the SEC referred to above. We also maintain a website at www.in8bio.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

# IN8BIO, INC.

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# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders IN8bio, Inc.

# **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of IN8bio, Inc. (the "Company") as of December 31, 2019 and 2020, and the related statements of operations, changes in convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as "the financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP We have served as the Company's auditor since January 2017.

Tysons, Virginia March 31, 2021

# **BALANCE SHEETS**

(in thousands except for per share data)

	Year ended [	December 31,
	2019	2020
Assets		
Current assets		
Cash	\$ 610	\$ 17,994
Prepaid expenses and other current assets	153	150
Total Current Assets	763	18,144
Non-current assets		
Property and equipment, net	274	186
Deferred offering costs	_	2,439
Other non-current assets	93	141
Total Non-Current Assets	367	2,766
Total Assets	\$ 1,130	\$ 20,910
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Liabilities		
Current liabilities		
Accounts payable	\$ 560	\$ 620
Accrued expenses and other current liabilities	87	1,778
Loan payable	_	174
Total Current Liabilities	647	2,572
Deferred rent	_	17
Warrant liability	829	_
Total Liabilities	1,476	2,589
Commitments and Contingencies  Convertible preferred stock, par value \$0.0001 per share; 7,435,616 and 27,564,260 shares authorized at December 31, 2019 and 2020, respectively; 2,713,980 shares and 9,993,727 shares, issued and outstanding at December 31, 2019 and 2020, and a liquidation preference of \$10,931 and \$37,969 at December 31, 2019 and 2020, respectively	8,896	34,900
Stockholders' Deficit		
Common stock, par value \$0.0001 per share; 27,000,000 and 50,700,000 shares authorized at December 31, 2019 and 2020, respectively; 3,235,671 and 3,764,488 shares issued and outstanding at December 31, 2019 and 2020, respectively	1	1
Additional paid-in capital	238	1,458
Accumulated deficit	(9,481)	(18,038)
Total Stockholders' Deficit	(9,242)	(16,579)
Total Liabilities, Convertible Preferred Stock and Stockholders' Deficit	\$ 1,130	\$ 20,910

# STATEMENTS OF OPERATIONS

(in thousands except for share and per share data)

	Year ended December 31,		mber 31,	
		2019		2020
Operating expenses				
Research and development	\$	2,358	\$	5,378
General and administrative		2,708		3,179
Loss on disposal of property and equipment		68		
Total operating expenses		5,134		8,557
Loss from operations		(5,134)		(8,557)
Net loss	\$	(5,134)	\$	(8,557)
Net loss attributable to common stockholders – basic and diluted (Note 12)	\$	(5,912)	\$	(10,340)
Net loss per share attributable to common stockholders – basic and diluted	\$	(1.85)	\$	(3.02)
Weighted-average shares of common stock – basic and diluted	3	,188,165	3	3,419,075

# STATEMENT OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(in thousands, except share data)

	Convertible Pre	eferred Stock	Common	Stock			
	Serie	s A	Class	Class A Additional Paid- Accur		Accumulated	
	Shares	Amount	Shares	Amount	in-Capital	Deficit	Total
Balance at January 1, 2019	2,713,980	\$ 8,896	3,174,751	\$ 1	\$ 97	\$ (4,347)	\$ (4,249)
Exercise of common stock – Class A	_	_	60,920	_	65	_	65
Stock-based compensation expense	_	_	_	_	76	_	76
Net loss	_	_	_	_	_	(5,134)	(5,134)
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	_	_	227,010	_	499	_	499
Issuance of common stock – Class A in relation to license agreement	_	_	89,629	_	103	_	103
Issuance of common stock – Class A in relation to legal settlement	_	_	200,750	_	248	_	248
Exercise of common stock option – Class A	_	_	11,428	_	13	_	13
Issuance of convertible preferred stock – Series A, net of \$81 issuance cost	7,048,351	25,175	_	_	_	_	_
Exercise of warrants into convertible preferred stock – Series A	231,396	829	_	_	_	_	_
Stock-based compensation expense	_	_	_	_	357	_	357
Net loss	_	_	_	_	_	(8,557)	(8,557)
Balance at December 31, 2020	9,993,727	\$34,900	3,764,488	\$ 1	\$1,458	\$(18,038)	\$(16,579)

# STATEMENTS OF CASH FLOWS

(in thousands)

	Year ended De	ecember 31,
	2019	2020
Cash flows from operating activities		
Net loss	\$(5,134)	\$ (8,557
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	96	88
Loss on disposal of property and equipment	68	_
Non-cash stock-based compensation	76	357
Non-cash stock issuance related to license agreement	_	103
Non-cash stock issuance related to legal settlement	_	248
Deferred rent	_	17
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(100)	3
Other non-current assets	(65)	(48
Other receivable	30	_
Accounts payable	141	(160
Accrued expenses and other current liabilities	87	816
Net cash used in operating activities	(4,801)	(7,133
Cash flows from investing activities		
Purchase of property and equipment	(330)	_
Proceeds from disposal of property and equipment	686	_
Net cash provided by investing activities	356	_
Cash flows from financing activities		
Proceeds from exercise of common stock options	65	13
Proceeds from issuance of common stock	_	499
Proceeds from issuance of loan	_	174
Proceeds from issuance of preferred stock, net of \$81 of issuance costs	_	25,175
Payment of deferred offering costs	_	(1,344
Net cash provided by financing activities	65	24,517
Net (decrease) increase in cash and restricted cash	(4,380)	17,384
Cash and restricted cash, beginning of year	4,990	610
Cash and restricted cash, end of year	\$ 610	\$17,994
Supplemental disclosure of noncash financing activities		
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 1.095
Exercise of convertible preferred stock warrants	_	829
		020

# **NOTES TO FINANCIAL STATEMENTS**

# 1. Organization and Nature of Operations

# Organization and Business

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. (the "Company") 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.

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.

#### COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, has spread worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. The outbreak and government measures taken in response have 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 future progression of the pandemic and its effects on the Company's business and operations are uncertain.

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 would disrupt its clinical supply chain or the availability or cost of materials, and it may affect the Company's ability to timely complete its clinical trials and delay the initiation and/or enrollment of any future clinical trials, disrupt regulatory activities or have other adverse effects on its business and operations.

The Company is monitoring 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 impact its business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

# Liquidity

Through December 31, 2020, the Company has funded its operations primarily with proceeds from the initial closing and additional closings of our Series A convertible preferred stock financing ("Series A Financing") and through its license agreements. The Company has incurred recurring losses and negative operating cash flows from operations since its inception, including net losses of \$5.1 million and \$8.6 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, the Company had an accumulated deficit of \$18.0 million. The Company expects to continue to generate operating losses for the foreseeable future.

# **NOTES TO FINANCIAL STATEMENTS**

# 1. Organization and Nature of Operations (Continued)

As of March 31, 2021, the issuance date of these financial statements for the year ended December 31, 2020, the Company expects that its cash will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

# Reverse Stock Split

On November 5, 2020, the Company effected a 0.365-for-1 reverse stock split of the Company's common stock and preferred stock, and the conversion price for the preferred stock was adjusted. All shares, stock options, warrants and per share information presented in the financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value and authorized number of shares of the Company's common stock and preferred stock.

# 2. Summary of Significant Accounting Policies

# Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

# Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions include the useful lives of property and equipment, deferred tax assets and liabilities and related valuation allowance, fair value of common stock and stock-based compensation, warrant liability and accrued research and development costs. Management bases its estimates on historical experience and on various other market-specific relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

# Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash. The Company's cash is maintained with a high quality, accredited financial institution. These amounts, at times, may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to significant risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements. Management deems there to be minimal credit risk associated with the Company's cash.

# Cash and Restricted Cash

Cash consists of standard checking accounts. The Company has restricted cash of \$0.1 million in the form of a security deposit related to its agreement with an equipment rental company for the years ended December 31, 2019 and 2020, respectively. These amounts have been classified as non-current assets on the Company's balance sheets.

# **Property and Equipment**

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

# NOTES TO FINANCIAL STATEMENTS

# 2. Summary of Significant Accounting Policies (Continued)

Computer equipment 3 years
Laboratory equipment 3-5 years

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

# Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. There were no impairments recorded for the years ended December 31, 2019 and 2020.

# Research and Development Costs

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

The Company analyzes the progress of clinical trials, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. The Company makes significant judgments and estimates in determining the accrued balance and expense in each accounting period. As actual costs become known, the Company adjusts the accrued estimates. Although the Company does not expect the estimates to be materially different from amounts actually incurred, the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from the Company's estimates and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers.

# Leases

The payments on operating lease agreements are recognized as an expense on a straight-line basis over the lease term. Associated costs, such as maintenance and insurance, are expensed as incurred

The Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability for its operating leases.

# Fair Value of Financial Instruments

The Company applies fair value accounting for all financial assets and liabilities and nonfinancial assets and liabilities that are required to be disclosed at fair value in the financial statements, Fair value is the price at which an asset could be exchanged, or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

# **NOTES TO FINANCIAL STATEMENTS**

# 2. Summary of Significant Accounting Policies (Continued)

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2 Inputs are other than quoted prices included in Level 1, which are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The Company's financial instruments include cash and restricted cash, accounts payable, and warrant liability. The Company's warrant liability was carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying amounts of cash, restricted cash, and accounts payable approximate fair value due to the short-term nature of these instruments.

#### **Income Taxes**

The Company utilizes the asset and liability method of accounting for income taxes. This method requires recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The Company evaluates its ability to benefit from all deferred tax assets and establishes valuation allowances for amounts it believes may not be realizable.

The Company recognizes the financial statement benefit of an income tax position only after determining that the relevant taxing authority would more-likely-than-not sustain the position following audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require application of significant judgment. The Company is subject to U.S. federal and various state and local jurisdictions. Due to the Company's net operating loss carryforwards, the Company may be subject to examination by authorities for all previously filed income tax returns.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was signed into law in response to the COVID-19 pandemic. The CARES Act provides numerous tax provisions and stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses, temporary changes to the prior and future limitations on interest deductions, and technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property. The Company has evaluated the provisions of the CARES Act relating to income taxes which will result in adjustments to certain deferred tax assets and liabilities. Due to the Company's U.S. valuation allowance, the Company noted the provisions of the CARES Act did not have a material impact on its financial statements.

# **NOTES TO FINANCIAL STATEMENTS**

# 2. Summary of Significant Accounting Policies (Continued)

# Stock-Based Compensation

The Company measures all stock-based awards granted to employees, nonemployees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The stock-based compensation expense is accounted for in the statements of operations based on the awards' grant date fair values. The Company accounts for forfeitures as they occur by reversing any expense recognized for unvested awards.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company uses the simplified method as allowed by the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

#### Warrants

The Company accounts for warrants on capital stock based on guidelines provided in ASC Topic 815, *Derivatives and Hedging — Contracts in Entity's Own Equity* ("ASC 815"), which provides guidance on contracts that are settled in the Company's own shares as either a liability or as an equity instrument depending on the warrant agreement. The Company uses the Black-Scholes pricing model, depending on the applicable terms of the warrant agreement, to value the warrants.

# **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. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. As of December 31, 2019 and 2020, the Company had deferred offering costs of \$0 and \$2.4 million, respectively.

# **Accounting Pronouncements Recently Adopted**

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). These amendments expand the scope of Topic 718, Compensation — Stock Compensation, which currently only includes share-based payments to employees, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, *Equity — Equity-Based Payments to Non-Employees*. This standard is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, with early

# **NOTES TO FINANCIAL STATEMENTS**

# 2. Summary of Significant Accounting Policies (Continued)

adoption permitted as long as ASU 2014-09 has been adopted by the Company. The Company adopted ASU 2018-07 as of January 1, 2019, which did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. The amendment of ASU 2018-13 removes disclosure requirements from Topic 820 in the areas of (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The guidance was adopted on January 1, 2020 and did not have a material impact on the Company's financial statements.

# **Accounting Pronouncements Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC 842"), which amends the existing accounting standards for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standard. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statement and provides for certain practical expedients. The guidance is effective for reporting periods beginning after December 15, 2020 for private companies with early adoption permitted. The Company adopted this standard on January 1, 2021.

The Company has completed its assessment of the impact ASU 2016-02 will have on its financial position, results of operations, and related footnotes. The Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company made an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company's assessment included identifying the Company's lease population, assessing significant leases under the new guidance and identifying changes to processes and controls. The adoption of the new standard will result in the recognition of right-of-use assets and lease liabilities of approximately \$1.7 million and \$1.8 million, as of December 31, 2019 and 2020, respectively, on the Company's balance sheet. The adoption of the new standard will not have a material impact on the Company's statement of operations or its liquidity.

In December 2019, the FASB issued ASU 2019-12, *Simplifications for Income Taxes* ("ASU 2019-12") guidance simplifying the accounting for income taxes, specifically with respect to intra-period tax allocation, income tax provisions provided for in interim financial statements, and franchise and other taxes partially based on income. The guidance is effective for reporting periods beginning after December 15, 2021. The Company is currently evaluating the impact, if any, that the adoption of this quidance will have on the financial statements.

# **NOTES TO FINANCIAL STATEMENTS**

#### 3. Fair Value of Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2019 (in thousands):

Description Liability	December 31, 2019	Quoted prices active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Warrant liability	\$829	\$—	\$—	\$829
Total financial liabilities	\$829	\$—	\$—	\$829

The fair value of the Series A convertible preferred stock ("Series A Preferred Stock") warrants upon issuance was \$0.8 million, which was determined using the intrinsic value because the exercise price was only \$0.0003 per share. The intrinsic value was calculated by taking the fair value of the underlying Series A Preferred Stock of \$3.5833 per share less the exercise price of \$0.0003 per share. The fair value of the Series A Preferred Stock was based on the price paid by investors and has not changed since issuance. Accordingly, there have been no changes in the fair value of the warrant liability for the year ended December 31, 2019. 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. As of December 31, 2020, there were no remaining warrants outstanding.

During the years ended December 31, 2019 and 2020, the Company had one additional Level 3 financial instrument remeasured on a recurring basis, which consisted of an antidilution liability related to an antidilution provision in the license agreement with UAB Research Foundation ("UABRF") (see Note 10). Both instruments were deemed immaterial, based on the remote probability of the occurrence of underlying events. The antidilution liability was settled in connection with the Company's Series A Preferred Stock issuances during the year ended December 31, 2020. There were no transfers between fair value hierarchy levels during the years ended December 31, 2019 and 2020.

# 4. Property and Equipment

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

	December 31, 2019	December 31, 2020
Machinery and equipment	\$ 443	\$ 443
Less accumulated depreciation	(169)	(257)
Property and equipment, net	\$ 274	\$ 186

Depreciation expense for property and equipment totaled \$0.1 million for each of the years ended December 31, 2019 and 2020.

# **NOTES TO FINANCIAL STATEMENTS**

# 5. Accrued Expenses and Other Current Liabilities

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

	December 31, 2019	December 31, 2020
Accrued offering costs	\$-	\$ 876
Accrued clinical trials	_	376
Accrued compensation	87	400
Accrued other	_	126
Total accrued expenses and other current liabilities	\$87	\$1,778

# 6. Loan Payable

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. The Company plans to pay back the full amount of the Loan in 2021.

Loan payable consists of the following (in thousands except year and percentage):

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

# 7. Convertible Preferred Stock

# Convertible Series A Preferred Stock

From January through August 2020, the Company issued 7,048,351 shares of Series A Preferred Stock at \$3.5833 per share for \$25.3 million in gross proceeds related to the Series A Preferred Stock issuance from 2018.

At December 31, 2020, a total of \$35.0 million, at \$3.5833 per share, had been raised by the Company through the Series A preferred financing and/or the Company issued Note Series 2018A convertible promissory note conversion that converted into Series A Preferred Stock on May 7, 2018 following the Domestication. The Series A Preferred Stock includes 2,713,980 and 9,993,727 shares issued and outstanding on December 31, 2019 and 2020, respectively.

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

# NOTES TO FINANCIAL STATEMENTS

# 7. Convertible Preferred Stock (Continued)

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

# NOTES TO FINANCIAL STATEMENTS

# 7. Convertible Preferred Stock (Continued)

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.

# 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.

The Series A Preferred Stock automatically converts to common stock, at the then effective conversion rate, upon (i) the written request of a majority of the outstanding shares of the Series A Preferred Stock voting as a single class or (ii) an initial public offering resulting in gross proceeds to the Company of at least \$25.0 million. 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

# NOTES TO FINANCIAL STATEMENTS

# 7. Convertible Preferred Stock (Continued)

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 are subject to an earlier expiration upon the closing of the Company's qualifying initial public offering of common stock. As of December 31, 2019, the Company had 231,396 warrants outstanding, with a fair value of \$0.8 million. 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 (see Note 3).

# 8. Common Stock

The Company has 27,000,000 and 50,700,000 authorized shares of common stock, par value \$0.0001 per share, of which 3,235,671 and 3,764,488 shares were issued and outstanding as of December 31, 2019 and 2020, respectively.

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.

In August 2020, the Company increased the authorized shares of common stock, par value \$0.0001 per share, to 50,700,000 shares.

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.

# 9. 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 817,126 and 2,101,478 shares were authorized under the 2018 Plan and 393,593 and 854,320 shares are available for granting of stock awards as of December 31, 2019 and 2020, respectively. The 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 Company's stock option activity for the years ended December 31, 2019 and 2020 (in thousands, except years, share and per share data):

	Options	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2019	237,773	\$1.07	9.86	\$ —
Granted	287,788	\$1.08	9.32	
Exercised	(60,921)	\$1.08	0.91	
Cancelled	(102,029)	\$1.08	9.33	
Outstanding as of December 31, 2019	362,611	\$1.08	9.22	\$ 5
Granted	929.806	\$6.56	9.74	

# **NOTES TO FINANCIAL STATEMENTS**

# 9. Stock-Based Compensation (Continued)

	Options	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate Intrinsic Value
Exercised	(11,428)	\$1.09	8.78	
Cancelled	(33,831)	\$1.08	9.02	
Outstanding as of December 31, 2020	1,247,158	\$5.16	9.34	\$1,486
Exercisable at December 31, 2020	149,686	\$1.78	8.28	\$ 562
Nonvested at December 31, 2020	1,097,472	\$5.63	9.49	\$ 924

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 years ended December 31, 2019 and 2020 was \$0.77 and \$4.67, 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. The aggregate intrinsic value of stock options exercised in the years ended December 31, 2019 and 2020 was \$1,919 and \$48,741 respectively.

The total fair value of options vested during the years ended December 31, 2019 and 2020 was \$49,283 and \$0.2 million, respectively.

# Stock-Based Compensation Expense

A summary of the assumptions used in determining the fair value of stock options granted in the period is as follows for the years ended December 31, 2019 and 2020:

	December 31, 2019	December 31, 2020
Expected dividend yield	_	_
Expected volatility	81.9% - 90.1%	83.3% - 90.9%
Risk-free interest rate	1.6% - 2.5%	0.3% - 1.4%
Expected average life (in years)	5.98 - 8.97	4.25 - 9.34

The Company recorded stock-based compensation as follows (in thousands):

	December 31, 2019	December 31, 2020
Research and development	\$50	\$192
General and administrative	26	165
Total	\$76	\$357

No related tax benefits from stock-based compensation expense were recognized for the years ended December 31, 2019 and 2020. As of December 31, 2020, there was \$4.2 million in unrecognized stock-based compensation cost, which is expected to be recognized over a weighted-average period of 3.30 years.

# 10. 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 the Emory University, Children's Healthcare of Atlanta, Inc. and UAB, as amended from time to time (the "Emory License

# **NOTES TO FINANCIAL STATEMENTS**

# 10. License Agreements (Continued)

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 the 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 our 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.

# **NOTES TO FINANCIAL STATEMENTS**

# 10. License Agreements (Continued)

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 years ended December 31, 2019 and 2020, the Company issued 0 and 89,629 shares of common stock, respectively, for 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 as of December 31, 2019 and 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.

# 11. Income Taxes

For the years ended December 31, 2019 and 2020, the tax provision (benefit) consisted of (in thousands):

	December 31, 2019	December 31, 2020
Current provision (benefit):		
Federal	\$ —	\$ —
State	_	_
Total	_	_
Deferred provision (benefit):		
Federal	(845)	(1,569)
State	(600)	(1,116)
Total	(1,445)	(2,685)
Change in valuation allowance	1,445	2,685
Income tax provision (benefit)	\$ —	\$ —

# **NOTES TO FINANCIAL STATEMENTS**

# 11. Income Taxes (Continued)

The items accounting for the difference between income taxes computed at the federal statutory rate and the Company's effective tax rate for 2019 and 2020 were as follows:

	December 31, 2019	December 31, 2020
U.S Federal statutory rate	21%	21%
State taxes, net of Federal Benefit	10%	10%
Non-deductible expenses	(1)%	6 0%
Change in valuation allowance	(30)%	6 (31)%
Effective rate	0%	0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial statement purposes and the amounts used for income tax purposes.

Components of the Company's net deferred tax assets (liabilities) balance are as follows at December 31, 2018 and 2019 (in thousands):

	December 31 2019	L, December 31, 2020
Deferred tax assets:		
Stock-based compensation	\$ 1	4 \$ 155
Net operating loss carryforwards and alternative minimum tax credits	2,08	9 4,667
Total deferred tax assets	2,10	3 4,822
Deferred tax liabilities:		
Property and equipment	(	5) (38)
Total deferred tax liabilities	(	5) (38)
Valuation allowance	(2,09	8) (4,784)
Deferred tax assets (liabilities), net	\$ -	- \$ -

The CARES Act, among other things, permits net operating loss ("NOL") carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The Company is currently evaluating the impact of the CARES Act, but at present, does not expect to benefit from the NOL carryback provisions.

As of December 31, 2020, the Company had federal NOL carryforwards of approximately \$14.9 million, New York State NOL carryforwards of approximately \$14.9 million, and New York City NOL carryforwards of approximately \$14.9 million. However, the Company's ability to utilize these NOLs will be dependent on the Company's ability to generate future taxable income. Furthermore, the utilization of these NOLs may also be limited in the future.

# 12. 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.

# NOTES TO FINANCIAL STATEMENTS

# 12. Net Loss Per Share (Continued)

The Company has calculated basic and diluted loss per share for the years ended December 31, 2019 and 2020 as follows (in thousands, except share and per share data):

		December 31, 2019		December 31, 2020		
Numerator:						
Net loss	\$	(5,134)	\$	(8,557)		
Less: Accruals of dividends of preferred stock		(778)		(1,783)		
Net loss attributable to common stockholders – basic and diluted	\$	(5,912)	\$	(10,340)		
Denominator:						
Weighted-average common stock outstanding	3,	188,165	3	,419,075		
Net loss per share attributable to common stockholders – basic and diluted	\$	(1.85)	\$	(3.02)		

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been antidilutive:

	December 31, 2019	December 31, 2020
Convertible preferred stock on an if converted basis	2,999,149	9,993,727
Stock options to purchase common stock	362,611	1,247,158
Warrants to purchase preferred stock	231,396	_

# 13. 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.

# Litigation Disclosure

# Incyte Corporation

In April 2019, Incyte Corporation ("Incyte") filed an opposition to the Company's pending application at the United States Patent and Trademark Office to register the mark INCYSUS alleging that the INCYSUS mark was likely to give rise to confusion in the marketplace with Incyte and, consequently, the mark should not proceed to registration. On April 24, 2019, Incyte also filed an opposition on similar grounds to the Company's pending application to register INCYSUS in the European Union. The parties settled this matter out of court on November 26, 2019 pursuant to which both parties dismissed the above noted actions and the Company agreed to cease use of the INCYSUS mark by August 26, 2020.

# Other Settlement

In July 2020, the Company entered into a settlement agreement with a former employee for \$0.3 million in cash and 200,750 shares of common stock.

# Lease Commitment Disclosure

# **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

# **NOTES TO FINANCIAL STATEMENTS**

# 13. Commitments and Contingencies (Continued)

leases. As of December 31, 2020, the Company had completed the sale and leaseback for four pieces of equipment and is leasing two 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 for each of the years ended December 31, 2019 and 2020. They are included in other non-current assets on the 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

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 year ended December 31, 2020, which are included in non-current assets on the balance sheets.

The following table summarizes the approximate future minimum rentals under the equipment and operating leases in effect at December 31, 2020 (in thousands):

	<u>Am</u>	ounts
2021	\$	832
2022		562
2023		365
2024		230
2025		236
Thereafter		41
Total minimum payments	\$2	2,266

# 14. Subsequent Events

expenses and utilities.

The Company has evaluated subsequent events from the balance sheet date through March 31, 2021, the date at which the financial statements were available to be issued, and has not identified any requiring disclosure.

# **CONDENSED INTERIM BALANCE SHEETS**

(in thousands except for share and per share data)

	As of		
	December 31 2020	2021	
A		(unaudited)	
Assets			
Current assets Cash	\$ 17,994	\$ 15,052	
Prepaid expenses and other current assets	150		
Total Current Assets	18,144		
Non-current assets	10,144	15,572	
Property and equipment, net	186	164	
Deferred offering costs	2,439		
Right of use assets – financing leases	2,400	819	
Right of use assets – operating leases	_	793	
Other non-current assets	141		
Total Non-Current Assets	2,766	5,051	
Total Assets	\$ 20,910		
Liabilities, Convertible Preferred Stock and Stockholders' Deficit			
Liabilities  Comment link like in			
Current liabilities	\$ 620	\$ 660	
Accounts payable	, ,	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Accrued expenses and other current liabilities	1,778	1,632	
Short-term financing lease liabilities	_	130	
Short-term operating lease liabilities  Loan payable, current	174		
	-		
Total Current Liabilities	2,572		
Deferred rent	17		
Long-term financing lease liabilities		309	
Long-term operating lease liabilities		733	
Total Liabilities	2,589	4,104	
Commitments and Contingencies			
Convertible preferred stock, par value \$0.0001 per share; 27,564,260 shares authorized, 9,993,727 shares, issued and outstanding at December 31, 2020 and March 31, 2021, and a liquidation preference of \$37,969 and	24.000	24,000	
\$38,676 at December 31, 2020 and March 31, 2021, respectively	34,900	34,900	
Stockholders' Deficit Common stock par value \$0,0001 per chara: 50,700,000 shares authorized			
Common stock, par value \$0.0001 per share; 50,700,000 shares authorized, 3,764,488 shares issued and outstanding at December 31, 2020 and			
March 31, 2021	1	. 1	
Additional paid-in capital	1,458	1,819	
Accumulated deficit	(18,038	(20,401)	
Total Stockholders' Deficit	(16,579		
Total Liabilities, Convertible Preferred Stock and Stockholders'			
Deficit	\$ 20,910	\$ 20,423	

# CONDENSED INTERIM STATEMENTS OF OPERATIONS

(in thousands except for share and per share data)

	Thre	Three Months Ended March 31,		
		2020	2021	
		(unaud	dited)	
Operating expenses				
Research and development	\$	1,052	\$	1,245
General and administrative		639		1,118
Total operating expenses		1,691		2,363
Loss from operations		(1,691)		(2,363)
Net loss	\$	(1,691)	\$	(2,363)
Net loss attributable to common stockholders – basic and diluted (Note 10)	\$	(1,951)	\$	(3,069)
Net loss per share attributable to common stockholders – basic and diluted	\$	(0.59)	\$	(0.82)
Weighted-average shares of common stock – basic and diluted	3,	305,367	3,	764,488

# CONDENSED INTERIM STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Common Stock				
	Series	Α	Class	s A Additiona Paid-in-		Accumulated			
	Shares	Amount	Shares	Amount	Capital	Deficit	Total		
Balance at January 1, 2020	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 cost	1,533,947	5,480	_	_	_	_	_		
Stock-based compensation expense	_	_	_	_	18	_	18		
Net loss	_	_	_	_	_	(1,691)	(1,691)		
Balance at March 31, 2020 (unaudited)	4,247,927	\$14,376	3,462,182	\$ 1	\$ 456	\$(11,172)	\$(10,715)		
Balance at January 1, 2021	9,993,727	\$34,900	3,764,488	\$ 1		\$(18,038)			
Stock-based compensation expense	_	_	_	_	361	_	361		
Net loss						(2,363)	(2,363)		
Balance at March 31, 2021 (unaudited)	9,993,727	\$34,900	3,764,488	\$ 1	\$1,819	\$(20,401)	\$(18,581)		

# CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31		
	2020	2021	
	(unaudit	ted)	
Cash flows from operating activities			
Net loss	\$(1,691)	\$ (2,363)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	22	22	
Non-cash stock-based compensation	18	361	
Amortization of financing lease right-of-use assets	_	113	
Amortization of operating lease right-of-use assets	_	30	
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	65	(162)	
Other non-current assets	(48)	(52	
Accounts payable	(60)	(180	
Accrued expenses and other current liabilities	71	(298	
Short-term operating lease liabilities	_	57	
Long-term operating lease liabilities		(35	
Net cash used in operating activities	(1,623)	(2,507	
Cash flows from financing activities			
Proceeds from exercise of common stock options – Class A	200	_	
Proceeds from issuance of preferred stock – Series A, net of \$16 of issuance costs	5,480	_	
Payments of financing lease obligations	_	(112	
Payment of deferred offering costs	_	(323	
Net cash provided by (used in) financing activities	5,680	(435	
Net increase (decrease) in cash and restricted cash	4,057	(2,942	
Cash and restricted cash, beginning of period	610	17,994	
Cash and restricted cash, end of period	\$ 4,667	\$15,052	
Supplemental disclosure of noncash financing activities			
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 1,238	
Initial measurement of operating lease right-of-use assets and liabilities	\$ —	\$ 3,483	

# NOTES TO CONDENSED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# 1. Organization and Nature of Operations

# Organization and Business

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. (the "Company") 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.

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.

#### COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, has spread worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. The outbreak and government measures taken in response have 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 future progression of the pandemic and its effects on the Company's business and operations are uncertain.

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 would disrupt its clinical supply chain or the availability or cost of materials, and it may affect the Company's ability to timely complete its clinical trials and delay the initiation and/or enrollment of any future clinical trials, disrupt regulatory activities or have other adverse effects on its business and operations.

The Company is monitoring 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 impact its business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

# Liquidity

Through March 31, 2021, the Company has funded its operations primarily with proceeds from the initial closing and additional closings of our Series A convertible preferred stock financing ("Series A Financing") and through its license agreements. The Company has incurred recurring losses and negative operating cash flows from operations since its inception, including net losses of \$1.7 million and \$2.4 million for the three months ended March 31, 2020 and 2021, respectively. As of March 31, 2021, the Company had an accumulated deficit of \$20.4 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of the issuance date of these financial statements, the Company expects that its cash will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

# Reverse Stock Split

On November 5, 2020, the Company effected a 0.365-for-1 reverse stock split of the Company's common stock and preferred stock, and the conversion price for the preferred stock was adjusted. All shares, stock options, warrants and per share information presented in the financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value and authorized number of shares of the Company's common stock and preferred stock.

# 2. Summary of Significant Accounting Policies

# Basis of Presentation

The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In management's opinion, the accompanying unaudited condensed interim financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The unaudited interim condensed results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC"). Management believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed interim financial statements are read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2020.

# Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2020, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

#### Leases

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 guidance under 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 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. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. As of December 31, 2020 and March 31, 2021, the Company had deferred offering costs of \$2.4 million and \$3.1 million, respectively.

# 3. Property and Equipment

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

	December 31, 2020	March 31, 2021
Machinery and equipment	\$ 443	\$ 443
Less accumulated depreciation	(257)	(279)
Property and equipment, net	\$ 186	\$ 164

Depreciation expense for property and equipment totaled \$22,000 for the three months ended March 31, 2020 and 2021.

# 4. Accrued Expenses and Other Current Liabilities

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

	December 31, 2020	March 31, 2021
Accrued offering costs	\$ 876	\$1,028
Accrued clinical trials	376	415
Accrued compensation	400	170
Accrued other	126	19
Total accrued expenses and other current liabilities	\$1,778	\$1,632

# 5. Loan Payable

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. The Company plans to pay back the full amount of the Loan in 2021.

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

	Year of Maturity	Interest Rate	Outstanding Principal
Loan payable	2022	1.00%	\$174
Total loan payable			\$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 March 31, 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/or the Company issued Note Series 2018A convertible promissory note conversion 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 December 31, 2020 and March 31, 2021. 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.

The Series A Preferred Stock automatically converts to common stock, at the then effective conversion rate, upon (i) the written request of a majority of the outstanding shares of the Series A Preferred Stock voting as a single class or (ii) an initial public offering resulting in gross proceeds to the Company of at least \$25.0 million. 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 December 31, 2020 and March 31, 2021.

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.

In August 2020, the Company increased the authorized shares of common stock, par value \$0.0001 per share, to 50,700,000 shares.

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.

# 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 854,320 and 549,188 shares are available for granting of stock awards as of December 31, 2020 and March 31, 2021, 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 Company's stock option activity for the three months ended March 31, 2020 and 2021 (in thousands, except share and per share data):

	Options	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	362,611	\$1.08	9.22	\$ 5
Granted	1,825	\$1.10	9.85	
Exercised	_	_	_	
Cancelled	_	_	_	
Outstanding as of March 31, 2020	364,436	\$1.08	8.98	\$ 8
Exercisable at March 31, 2020	114,587	\$1.08	8.83	\$ 2
Nonvested at March 31, 2020	249,849	\$1.08	8.96	\$ 6
Outstanding as of January 1, 2021	1,247,158	\$5.16	9.34	\$1,486
Granted	305,152	\$5.36	9.84	
Exercised	_	_	_	
Cancelled				
Outstanding as of March 31, 2021	1,552,290	\$5.20	9.24	\$1,486
Exercisable at March 31, 2021	195,024	\$2.38	8.24	\$ 643
Nonvested at March 31, 2021	1,357,266	\$5.61	9.39	\$ 843

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 three months ended March 31, 2020 and 2021 is \$0.96 and \$4.02, 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.

The total fair value of options vested during the three months ended March 31, 2021 was \$0.2 million.

# Stock-Based Compensation Expense

A summary of the assumptions used in determining the fair value of stock options granted in the period is as follows for the three months ended March 31, 2020 and 2021:

	March 31, 2020	March 31, 2021
Expected dividend yield		_
Expected volatility	83.3%	88.78%
Risk-free interest rate	1.40%	0.67%
Expected average life (in years)	6.08	6.08

The Company recorded stock-based compensation as follows (in thousands):

	March 31, 2020	March 31, 2021
Research and development	\$16	\$168
General and administrative	2	193
Total	\$18	\$361

No related tax benefits from stock-based compensation expense were recognized for the three months ended March 31, 2020 and 2021. As of March 31, 2021, there was \$5.1 million in unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.24 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 the 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 the 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 our 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 three months ended March 31, 2020 and 2021, the Company did not issue any additional shares common stock in connection with the antidilution provision. As of March 31, 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 March 31, 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. 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.

The Company has calculated basic and diluted loss per share for the three months ended March 31, 2020 and 2021 as follows (in thousands, except share and per share data):

		arch 31, 2020	М	arch 31, 2021
Numerator:				
Net loss	\$	(1,691)	\$	(2,363)
Less: Accruals of dividends of preferred stock		(260)		(706)
Net loss attributable to common stockholders – basic and diluted	\$	(1,951)	\$	(3,069)
Denominator:				
Weighted-average common stock outstanding	3,	305,367	3	,764,488
Net loss per share attributable to common stockholders – basic and diluted	\$	(0.59)	\$	(0.82)

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been antidilutive:

	March 31, 2020	March 31, 2021
Convertible preferred stock on an if converted basis	4,247,927	9,993,727
Stock options to purchase common stock	364,436	1,552,290
Warrants to purchase preferred stock	231,396	

# 11. Commitments and Contingencies

# Intellectual Property

The Company has existing commitments to the licensors of the intellectual property which the Company has licensed. These commitments are based upon certain clinical research, regulatory, financial and sales milestones being achieved. Additionally, the Company is obligated to pay a single-digit royalty on commercial sales on a global basis. 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.

# **Litigation Disclosure**

# Incyte Corporation

In April 2019, Incyte Corporation ("Incyte") filed an opposition to the Company's pending application at the United States Patent and Trademark Office to register the mark INCYSUS alleging that the INCYSUS mark was likely to give rise to confusion in the marketplace with Incyte and, consequently, the mark should not proceed to registration. On April 24, 2019, Incyte also filed an opposition on similar grounds to the Company's pending application to register INCYSUS in the European Union. The parties settled this matter out of court on November 26, 2019 pursuant to which both parties dismissed the above noted actions and the Company agreed to cease use of the INCYSUS mark by August 26, 2020.

# Other Settlement

In July 2020, the Company entered into a settlement agreement with a former employee for \$0.3 million in cash and 200,750 shares of common stock.

# Lease Commitment Disclosure

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 March 31, 2021, the Company had completed the sale and leaseback for four pieces of equipment and is leasing two 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 December 31, 2020 and March 31, 2021. They are included in other non-current assets on the 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 three months ended March 31, 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 months ended March 31, 2021 (in thousands):

	Amounts
Lease Cost	
Financing lease costs:	
Amortization of finance right-of-use assets	\$113
Interest on finance lease liabilities	21
Operating lease costs	52
Short-term lease costs	115
Variable lease costs	<u> </u>
Total minimum payments	\$301
Other Lease Information	
Cash paid for amounts included in the measurement of lease liability – finance leases	\$ 21
Cash paid for amounts included in the measurement of lease liability – operating leases	\$ 133
Weighted-average remaining lease term – finance leases	1.86
Weighted-average remaining lease term – operating leases	4.92
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 March 31, 2021 (in thousands):

	Financing	Operating
2021	\$400	\$ 158
2022	315	216
2023	132	223
2024	_	230
2025	_	236
Thereafter	_	41
Total lease payments	847	1,104
Less: interest	(72)	(241)
Total lease liabilities	\$775	\$ 863

### 12. Subsequent Events

The Company has evaluated subsequent events and has not identified any requiring disclosures.

# **Shares**



## **Common Stock**

Prospectus

, 2021

**B. Riley Securities** 

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of our common stock being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and The Nasdaq Stock Market LLC, or Nasdaq, listing fee.

Item	P	Amount
SEC registration fee	\$	5,019
FINRA filing fee		14,246
Nasdaq listing fee		150,000
Printing expenses		150,000
Legal fees and expenses	2,	,000,000
Accounting fees and expenses		900,000
Miscellaneous expenses		580,735
Total	\$3,	800,000

#### Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law:
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- · any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other

things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

The Registrant has purchased and currently intends to maintain insurance on behalf of each and every person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of underwriting agreement for this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this registration statement for specified liabilities, including matters arising under the Securities Act.

#### Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since September 10, 2017 through the date of the prospectus that is a part of this registration statement:

- (1) We granted options to purchase an aggregate of 1,799,499 shares of common stock, with exercise prices ranging from \$1.07 to \$6.74 per share, to certain of our employees, directors and consultants pursuant to our 2018 Equity Incentive Plan, as amended, or the 2018 Plan. Of these, 72,349 shares have been issued pursuant to the exercises of options for cash consideration and 135,861 have been cancelled.
- (2) In April 2018, our predecessor entity issued an aggregate principal amount of approximately \$2.5 million of convertible notes, or the 2018A Notes, to 12 accredited investors. In May 2018, in connection with the closing of the Series A convertible preferred stock, or Series A Preferred Stock, financing described below, all 2018A Notes and the then accrued interest totaling approximately \$2.5 million, were converted into 694,212 shares of our Series A Preferred Stock.
- (3) Between May 2018 and August 2020, we issued an aggregate of 9,762,331 shares of our Series A Preferred Stock at a price per share of \$3.5833 for total gross proceeds of approximately \$32.5 million, excluding proceeds from the sale of the 2018A Notes, to 33 accredited investors.
- (4) In connection with the initial closing of the Series A Preferred Stock financing in May 2018, certain Series A investors were issued five-year warrants, entitling such individuals to purchase up to an aggregate of 231,396 shares of our Series A Preferred Stock at an exercise price of \$0.0003 per share.
- (5) In March 2020, we entered into a common stock purchase agreement with a member of our board of directors for the issuance and sale of 182,500 shares of our common stock for a total purchase price of \$200,000.
- (6) Between May 2018 and August 2020, we issued an aggregate of 151,382 shares of our common stock to The UAB Research Foundation as a result of certain antidilution provisions contained in our license agreement with The UAB Research Foundation.
- (7) In July 2020, we issued 200,750 shares of common stock to a former employee pursuant to the terms of a settlement agreement.

- (8) In October 2020, we entered into a common stock purchase agreement with a member of our board of directors for the issuance and sale of 29,674 shares of our common stock for a total purchase price of \$199,998.
- (9) In October 2020, we entered into a common stock purchase agreement for the issuance and sale of 14,837 shares of our common stock for a total purchase price of \$99,999.
- (10) In October 2020, we issued 231,396 shares of our Series A Preferred Stock upon the exercise of our outstanding warrants for cash consideration of \$0.0003 per share.

The offers, sales and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were employees, directors or bona fide consultants of the Registrant and received the securities under the 2018 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about the Registrant.

The offers, sales and issuances of the securities described in paragraphs (2) to (10) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, and with respect to paragraphs (3) and (4), also Rule 506 promulgated under Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about the Registrant. No underwriters were involved in these transactions.

#### Item 16. Exhibits and Financial Statement Schedules.

#### (a) Exhibits.

The exhibits listed below are filed as part of this registration statement.

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1#	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2#	Form of Amended and Restated Certificate of Incorporation, to be effective immediately after to the completion of this offering.
3.3#	Bylaws, as currently in effect.
3.4#	Form of Amended and Restated Bylaws, to be effective immediately prior to the completion of this offering.
4.1#	Form of Common Stock Certificate.
4.2#	Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated May 7, 2018.
5.1^	Opinion of Cooley LLP.
10.1+#	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers.
10.2+#	2018 Equity Incentive Plan.
10.3+#	Form of Stock Option Grant Notice and Option Agreement under 2018 Equity Incentive Plan.
10.4+#	2020 Equity Incentive Plan.
10.5+#	Forms of Option Grant Notice and Option Agreement under 2020 Equity Incentive Plan.

Exhibit Number	Description
10.6+#	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under 2020 Equity Incentive Plan.
10.7+#	2020 Employee Stock Purchase Plan.
10.8†#	Exclusive License Agreement, dated March 10, 2016, between the Registrant and The UAB Research Foundation, as amended.
10.9†#	First Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant.
10.10†#	Second Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant.
10.11†#	Third Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant.
10.12†#	Fourth Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant.
10.13†#	Exclusive License Agreement, dated June 10, 2016, between Emory University, Children's Healthcare of Atlanta, Inc., and UAB Research Foundation and the Registrant.
10.14†#	First Amendment to Exclusive License Agreement between Emory University, Children's Healthcare of Atlanta, Inc., The UAB Research Foundation and the Registrant.
10.15†#	Second Amendment to Exclusive License Agreement between Emory University, Children's Healthcare of Atlanta, Inc., The UAB Research Foundation and the Registrant.
10.16+#	Amended and Restated Employment Agreement, between Registrant and William Ho, dated December 1, 2020.
10.17+#	Amended and Restated Employment Agreement between Registrant and Lawrence Lamb, dated December 31, 2020.
10.18+#	Offer Letter to Melissa Beelen, dated December 21, 2020.
10.19+#	Non-Employee Director Compensation Policy.
23.1*	Consent of CohnReznick LLP, an Independent Registered Public Accounting Firm.
23.2^	Consent of Cooley LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on the signature page to this registration statement).

 <sup>\*</sup> Filed herewith.

#### (b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of

<sup>#</sup> Previously filed.

<sup>^</sup> To be filed by amendment.

<sup>+</sup> Indicates a management contract or compensatory plan.

<sup>†</sup> Portions of the exhibit (marked by asterisks) have been omitted pursuant to Regulation S-K Item 601(b)(2).

any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- For purposes of determining any liability under the Securities Act, the information omitted from
  the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A
  and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or
  (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration
  Statement as of the time it was declared effective.
- 2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this amendment no. 4 to the registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on this 19<sup>th</sup> day of July, 2021.

IN8BIO. INC.

,		
Ву:	/s/ William Ho	
	William Ho	

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this amendment no. 4 to this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ William Ho William Ho	President, Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	July 19, 2021
/s/ Patrick McCall	Chief Financial Officer	July 19, 2021
Patrick McCall	(Principal Financial and Accounting Officer)	
*	Chairman	July 19, 2021
Alan S. Roemer		
*	Director	July 19, 2021
Peter Brandt		
*	Director	July 19, 2021
Travis Whitfill		
*By: /s/ William Ho		
William Ho Attorney-in-Fact		

#### **POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints William Ho and Alan S. Roemer, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this amendment no. 4 to this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Emily T. Fairbairn	Director	July 19, 2021
Emily T. Fairbairn		
/s/ Luba Greenwood	Director	July 19, 2021
Luba Greenwood		

[•] shares

#### IN8BIO, INC.

#### **Common Stock**

#### **UNDERWRITING AGREEMENT**

 $[\bullet]$ , 2021

B. Riley Securities, Inc.

As Representative of the several Underwriters named in Schedule I attached hereto

c/o B. Riley Securities, Inc. 299 Park Avenue New York, New York 10171

Ladies and Gentlemen:

IN8bio, Inc., a Delaware corporation (the "Company"), proposes to sell [●] shares (the "Firm Stock") of the Company's common stock, par value \$0.0001 per share (the "Common Stock"). In addition, the Company proposes to grant to the underwriters named in Schedule I (the "Underwriters") attached to this agreement (this "Agreement") an option to purchase up to [●] additional shares of the Common Stock on the terms set forth in Section 3 (the "Option Stock"). The Firm Stock and the Option Stock, if purchased, are hereinafter collectively called the "Stock". This Agreement is to confirm the agreement concerning the purchase of the Stock from the Company by the Underwriters.

As used in this Agreement:

- (i) "Applicable Time" means [●] [A.M.][P.M.] (New York City time) on [•], 2021;
- (ii) "Effective Date" means the date and time as of which such registration statement was declared effective by the Commission;
- (iii) "Issuer Free Writing Prospectus" means each "issuer free writing prospectus" (as defined in Rule 433 under the Securities Act) relating to the Stock;
- (iv) "*Preliminary Prospectus*" means any preliminary prospectus relating to the Stock included in such registration statement or filed with the Commission pursuant to Rule 424(b) under the Securities Act;
- (v) "*Pricing Disclosure Package*" means, as of the Applicable Time, the most recent Preliminary Prospectus, together with the information included in Schedule II hereto, if any, and each Issuer Free Writing Prospectus filed or used by the Company at or before the Applicable Time, other than a road show, that is an Issuer Free Writing Prospectus but is not required to be filed under Rule 433 under the Securities Act;

- (vi) "*Prospectus*" means the final prospectus relating to the Stock, as filed with the Commission pursuant to Rule 424(b) under the Securities Act;
- (vii) "Registration Statement" means, collectively, the various parts of such registration statement, each as amended as of the Effective Date for such part, including any Preliminary Prospectus or the Prospectus, all exhibits to such registration statement and including the information deemed by virtue of Rule 430A under the Securities Act to be part of such registration statement as of the Effective Date;
- (viii) "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act or Rule 163B under the Securities Act; and
- (ix) "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

Any reference to the "most recent Preliminary Prospectus" shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement or filed pursuant to Rule 424(b) under the Securities Act prior to or on the date hereof. The Commission has not issued any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus or suspending the effectiveness of the Registration Statement, and no proceeding or examination for such purpose has been instituted or threatened by the Commission.

- 1. Representations, Warranties and Agreements of the Company. The Company represents, warrants and agrees that:
- (a) A registration statement on Form S-1 (File No. 333-249530) relating to the Stock has (i) been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations of the Securities and Exchange Commission (the "Commission") thereunder; (ii) been filed with the Commission under the Securities Act; and (iii) become effective under the Securities Act. Copies of such registration statement and any amendment thereto have been delivered by the Company to you as the representative (the "Representative") of the Underwriters.
- (b) From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and will be an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "*Emerging Growth Company*").

- (c) The Company (i) has not engaged in any Testing-the-Waters Communication other than, with the consent of the Representative, Testing-the-Waters Communications with entities that are, or are reasonably believed to be, qualified institutional buyers within the meaning of Rule 144A under the Securities Act, or with institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed or approved for distribution any Written Testing-the-Waters Communications other than those listed on Schedule V hereto.
- (d) The Company was not at the time of the initial filing of the Registration Statement and at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) under the Securities Act) of the Stock, is not on the date hereof and will not be on the applicable Delivery Date (as defined below), an "ineligible issuer" (as defined in Rule 405 under the Securities Act).
- (e) The Registration Statement conformed and will conform in all material respects on the Effective Date and on the applicable Delivery Date, and any amendment to the Registration Statement filed after the date hereof will conform in all material respects when filed, to the requirements of the Securities Act and the rules and regulations thereunder. The most recent Preliminary Prospectus conformed, and the Prospectus will conform, in all material respects when filed with the Commission pursuant to Rule 424(b) under the Securities Act and on the applicable Delivery Date, to the requirements of the Securities Act and the rules and regulations thereunder.
- (f) The Registration Statement did not, as of the Effective Date, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Registration Statement in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (g) The Prospectus will not, as of its date or as of the applicable Delivery Date, contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Prospectus in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (h) The Pricing Disclosure Package did not, as of the Applicable Time, contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Pricing Disclosure Package made in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).

- (i) Each Issuer Free Writing Prospectus listed in Schedule III hereto, when taken together with the Pricing Disclosure Package, did not, as of the Applicable Time, contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from such Issuer Free Writing Prospectus listed in Schedule III hereto in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (j) No Written Testing-the-Waters Communication, as of the Applicable Time, when taken together with the Pricing Disclosure Package, contained an untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from such Written Testing-the-Waters Communication listed on Schedule V hereto in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e); and the Company has filed publicly on the Commission's Electronic Data Gathering, Analysis, and Retrieval system ("*EDGAR*") at least 15 calendar days prior to any "road show" (as defined in Rule 433 under the Securities Act), any confidentially submitted registration statement amendments relating to the offer and sale of the Stock. Each Written Testing-the-Waters Communications did not, as of each date used include any information that materially conflicted, conflicts or will conflict with the information contained in the Registration Statement.
- (k) Each Issuer Free Writing Prospectus conformed or will conform, in all material respects, to the requirements of the Securities Act and the rules and regulations thereunder on the date of first use, and the Company has complied with all prospectus delivery and any filing requirements applicable to such Issuer Free Writing Prospectus pursuant to the Securities Act and rules and regulations thereunder. The Company has not made any offer relating to the Stock that would constitute an Issuer Free Writing Prospectus without the prior written consent of the Representative, except as set forth on Schedule IV hereto. The Company has retained in accordance with the Securities Act and the rules and regulations thereunder all Issuer Free Writing Prospectuses that were not required to be filed pursuant to the Securities Act and the rules and regulations thereunder. The Company has taken all actions necessary so that any "road show" (as defined in Rule 433 under the Securities Act) in connection with the offering of the Stock will not be required to be filed pursuant to the Securities Act and the rules and regulations thereunder.
- (l) The Company has been duly organized, is validly existing and in good standing as a corporation or other business entity under the laws of its jurisdiction of organization and is duly qualified to do business and in good standing as a foreign corporation or other business entity in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, except where the failure to be so qualified or in good standing could not, in the aggregate, reasonably be expected to have a material adverse effect on the condition (financial or otherwise), results of operations, stockholders' equity, properties, business or prospects of the Company taken as a whole (a "Material Adverse Effect"). The Company has all power and authority necessary to own or hold its properties and to conduct its business as described in the Pricing Disclosure Package. The Company does not own or control, directly or indirectly, any corporation, association or other entity.

- (m) The Company has an authorized capitalization as set forth under the heading "Capitalization" in each of the Pricing Disclosure Package and the Prospectus as of the date or dates set forth therein, and all of the issued shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and non-assessable, conform to the description thereof contained in the Pricing Disclosure Package and were issued in compliance with federal and state securities laws and not in violation of any preemptive right, resale right, right of first refusal or similar right. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued, conform to the description thereof contained in the Pricing Disclosure Package and were issued in compliance with federal and state securities laws.
- (n) The shares of the Stock to be issued and sold by the Company to the Underwriters hereunder have been duly authorized and, upon payment and delivery in accordance with this Agreement, will be validly issued, fully paid and non-assessable, will conform to the description thereof contained in the Pricing Disclosure Package and the Prospectus, will be issued in compliance with federal and state securities laws and will be free of statutory and contractual preemptive rights, rights of first refusal and similar rights.
- (o) The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. This Agreement has been duly and validly authorized, executed and delivered by the Company.
- (p) The issuance and sale of the Stock by the Company, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby and the application of the proceeds from the sale of the Stock as described under "Use of Proceeds" in the Pricing Disclosure Package and the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, impose any lien, charge or encumbrance upon any property or assets of the Company, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which the Company is a party or by which the Company is bound or to which any of the property or assets of the Company is subject; (ii) result in any violation of the provisions of the charter or by-laws (or similar organizational documents) of the Company; or (iii) result in any violation of any statute or any judgment, order, decree, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its properties or assets, except, with respect to clauses (i) and (iii), conflicts or violations that would not reasonably be expected to have a Material Adverse Effect.
- (q) No consent, approval, authorization or order of, or filing, registration or qualification with, any court or governmental agency or body having jurisdiction over the Company or any of its properties or assets is required for the issue and sale of the Stock by the Company, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby, the application of the proceeds from the sale of the Stock as described under "Use of Proceeds" in the Pricing Disclosure Package and the Prospectus, except for the registration of the Stock under the Securities Act and such consents, approvals, authorizations, orders, filings, registrations or qualifications as may be required under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and applicable state or foreign securities laws and/or the bylaws and rules of the Financial Industry Regulatory Authority, Inc. (the "FINRA") in connection with the purchase and sale of the Stock by the Underwriters.

- (r) The historical financial statements (including the related notes and supporting schedules) included in the Pricing Disclosure Package and the Prospectus comply as to form in all material respects with the requirements of Regulation S-X under the Securities Act and present fairly, in all material respects, the financial condition, results of operations and cash flows of the entities purported to be shown thereby at the dates and for the periods indicated and have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved. The supporting schedules, if any, present fairly, in all material respects, in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Pricing Disclosure Package and the Prospectus present fairly, in all material respects, the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein.
  - (s) [Reserved].
- (t) CohnReznick LLP, who have certified certain financial statements of the Company, whose report appears in the Pricing Disclosure Package and the Prospectus and who have delivered the initial letter referred to in Section 7(g) hereof, are independent public accountants as required by the Securities Act and the rules and regulations thereunder.
- (u) The Company maintains internal accounting controls designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with GAAP and to maintain accountability for its assets, (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. As of the date of the most recent balance sheet of the Company reviewed or audited by CohnReznick LLP, there were no material weaknesses in the Company's internal controls.
- (v) (i) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), (ii) such disclosure controls and procedures are designed to ensure that the information is accumulated and communicated to management of the Company, including their respective principal executive officers and principal financial officers, as appropriate, and (iii) such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established.

- (w) Since the date of the most recent balance sheet of the Company reviewed or audited by CohnReznick LLP, (i) the Company has not been advised of or become aware of (A) any significant deficiencies in the design or operation of internal controls that could adversely affect the ability of the Company to record, process, summarize and report financial data, or any material weaknesses in internal controls, or (B) any fraud, whether or not material, that involves management or other employees who have a significant role in the internal controls of the Company; and (ii) there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.
- The section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies" set forth in the Pricing Disclosure Package accurately and fully describes, in all material respects, (i) the accounting policies that the Company believes are the most important in the portrayal of the Company's financial condition and results of operations and that require management's most difficult, subjective or complex judgments ("Critical Accounting Policies"); (ii) the judgments and uncertainties affecting the application of Critical Accounting Policies; and (iii) the likelihood that materially different amounts would be reported under different conditions or using different assumptions and an explanation thereof.
- (y) There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith.
- (z) Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, since the date of the latest audited financial statements included in the most recent Preliminary Prospectus and the Prospectus, the Company has not (i) sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree (whether domestic or foreign), (ii) incurred any material liability or obligation, direct or contingent, other than liabilities and obligations that were incurred in the ordinary course of business, (iii) entered into any material transaction not in the ordinary course of business, or (iv) declared or paid any dividend on its capital stock, and since such date, there has not been any change in the capital stock, partnership or limited liability interests, as applicable, or long-term debt of the Company or any adverse change, or any development involving a prospective adverse change, in or affecting the condition (financial or otherwise), results of operations, stockholders' equity, properties, management, business or prospects of the Company taken as a whole, in each case except as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (aa) The Company does not own any real property. The Company has good and marketable title to all personal property owned by it, in each case free and clear of all liens, encumbrances and defects, except such liens, encumbrances and defects as are described in the Pricing Disclosure Package and the Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company. All assets held under lease by the Company are held under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made and proposed to be made of such assets by the Company.

- (bb) The Company has, and is operating in compliance with, such permits, licenses, patents, franchises, certificates of need and other approvals or authorizations of governmental or regulatory authorities ("*Permits*") as are necessary under applicable law to own its properties and conduct its businesses in the manner described in the Pricing Disclosure Package and the Prospectus, except for any of the foregoing that would not, in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has fulfilled and performed all of its obligations with respect to the Permits, and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the holder or any such Permits, except for any of the foregoing that would not reasonably be expected to have a Material Adverse Effect. The Company has not received written notice of any revocation or modification of any such Permits or has any reason to believe that any such Permits will not be renewed in the ordinary course.
- (cc) The Company owns or possesses adequate rights to use all material patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, know-how, inventions, domain names, software, systems and technology (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) necessary for the conduct of its businesses and has no reason to believe that the conduct of its respective businesses will conflict with, and has not received any notice of any claim of conflict with, any such rights of others.
- (dd) There are no legal or governmental proceedings pending to which the Company is a party or of which any property or assets of the Company is the subject that could, in the aggregate, reasonably be expected to have a Material Adverse Effect or could, in the aggregate, reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of the transactions contemplated hereby; and to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others.
- (ee) There are no contracts or other documents required to be described in the Registration Statement or the Pricing Disclosure Package or filed as exhibits to the Registration Statement, that are not described and filed as required. The statements made in the Pricing Disclosure Package, insofar as they purport to constitute summaries of the terms of the contracts and other documents described and filed, constitute accurate summaries of the terms of such contracts and documents in all material respects. The Company has no knowledge that any other party to any such contract or other document has any intention not to render full performance as contemplated by the terms thereof.
- (ff) The Company carries, or is covered by, insurance from insurers of recognized financial responsibility in such amounts and covering such risks as is, in the Company's reasonable judgment, adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries, and such insurance and related policies are in full force and effect. The Company is in compliance with the terms of such policies in all material respects; and the Company has not received written notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance; there are no claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that could not reasonably be expected to have a Material Adverse Effect.

- (gg) No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company, on the other hand, that is required to be described in the Pricing Disclosure Package and the Prospectus, which is not so described.
- (hh) No labor disturbance by or dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent that could reasonably be expected to have a Material Adverse Effect.
- (ii) The Company (i) is not in violation of its charter or by-laws (or similar organizational documents), (ii) is not in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant, condition or other obligation contained in any indenture, mortgage, deed of trust, loan agreement, license or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, (iii) is not in violation of any law, statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over it or its property or assets or its own privacy policies or (iv) has not failed to obtain any license, permit, certificate, franchise or other governmental authorization or permit necessary to the ownership of its property or to the conduct of its business, except in the case of clauses (ii), (iii) and (iv), to the extent any such conflict, breach, violation or default could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (jj) Except as described in the Pricing Disclosure Package and the Prospectus, (i) there are no proceedings that are pending, or to the Company's knowledge, contemplated, under any laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including without limitation any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to use, handling, storage, manufacturing, transportation, treatment, discharge, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws") in which a governmental authority is also a party, except as would not reasonably be expected to have a Material Adverse Effect, (ii) the Company is not aware of any issues regarding compliance with Environmental Laws, including any pending or proposed Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company, and (iii) the Company does not anticipate material capital expenditures relating to Environmental Laws.

- (kk) The Company has filed all federal, state, local and foreign tax returns required to be filed by it through the date hereof, subject to permitted extensions, and have paid all taxes due, and no tax deficiency has been determined adversely to the Company, nor does the Company have any knowledge of any tax deficiencies that have been, or could reasonably be expected to be asserted against the Company, that could, in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (i) Each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Security Act of 1974, as amended ("ERISA")) for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the "Code")) would have any liability (each a "Plan") has been maintained in compliance with its terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur, (B) no failure to meet the minimum funding standard set forth in Sections 412 of the Code and 303 of ERISA, whether or not waived, has occurred or is reasonably expected to occur, (C) no Plan is or is reasonably expected to be in "at risk" status (within the meaning of Section 430 of the Code or Section 303 of ERISA), (D) there has been no filing pursuant to Section 412(c) of the Code or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan or the receipt by the Company or any member of its Controlled Group from the PBGC or the Plan administrator of the notice relating to the intention to terminate any Plan or Plans or to appoint a trustee to administer any Plan, (E) no conditions contained in Section 303(k)(1)(A) of ERISA for the imposition of a lien shall have been met with respect to any Plan, (F) the fair market value of the assets under each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan) and (G) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(c)(3) of ERISA) ("Multiemployer Plan"); (iv) no Multiemployer Plan is, or is expected to be, "insolvent" (within the meaning of Section 4245 of ERISA), or in "endangered" or "critical" status (within the meaning of Section 432 of the Code or Section 304 of ERISA); and (v) each Plan that is intended to be qualified under Section 401(a) of the Code has received a favorable determination letter from the Internal Revenue Service that it is so qualified and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification, except, with respect to clauses (i) through (v), other than as could, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (mm) The statistical and market-related data included in the Pricing Disclosure Package, the Prospectus and "road show" (as defined in Rule 433 under the Securities Act) and the consolidated financial statements of the Company included in the Pricing Disclosure Package are based on or derived from sources that the Company reasonably believes to be reliable in all material respects.

- (nn) The Company is not, and as of the applicable Delivery Date and, after giving effect to the offer and sale of the Stock and the application of the proceeds therefrom as described under "Use of Proceeds" in the Pricing Disclosure Package and the Prospectus, will not be (i) an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "Investment Company Act"), and the rules and regulations of the Commission thereunder, or (ii) a "business development company" (as defined in Section 2(a)(48) of the Investment Company Act).
- (oo) The statements set forth in each of the most recent Preliminary Prospectus and the Prospectus under the caption "Description of Capital Stock", insofar as they purport to constitute a summary of the terms of the Shares, and under the captions "Material U.S. Federal Income Tax Consequences for Non-U.S. Holders" and "Underwriting", insofar as they purport to summarize the provisions of the laws and documents referred to therein, are accurate summaries in all material respects.
- (pp) Except as disclosed in the Registration Statement and the Pricing Disclosure Package, there are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights that have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.
- (qq) The Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against it or the Underwriters for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Stock.
- (rr) The Company has not sold or issued any securities that would be integrated with the offering of the Stock contemplated by this Agreement pursuant to the Securities Act, the rules and regulations thereunder or the interpretations thereof by the Commission.
- (ss) The Company and, to the Company's knowledge, its affiliates have not taken, directly or indirectly, any action designed to constitute or that has constituted, or that could reasonably be expected to cause or result in, the stabilization or manipulation of the price of any security of the Company in connection with the offering of the shares of the Stock.
- (tt) The Stock has been approved for listing, subject to official notice of and evidence of satisfactory distribution on, The Nasdaq Global Market.
- (uu) The Company has not distributed and, prior to the later to occur of any Delivery Date and completion of the distribution of the Stock, will not distribute any offering material in connection with the offering and sale of the Stock other than any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus to which the Representative have consented in accordance with Section 1(l) or 6(a)(vi) and any Issuer Free Writing Prospectus set forth on Schedule IV hereto.

- (vv) To the Company's knowledge, it is not in violation of, and the Company has not received notice of, any violation with respect to any federal or state law relating to discrimination in the hiring, promotion or pay of employees, nor any applicable federal or state wage and hour laws, nor any state law precluding the denial of credit due to the neighborhood in which a property is situated, the violation of any of which could reasonably be expected to have a Material Adverse Effect.
- (ww) Neither the Company nor any of the Company's directors or officers, nor, to the knowledge of the Company, any agents or employees of the Company, has in the course of its actions for, or on behalf of, the Company: (i) made any unlawful contribution, gift, or other unlawful expense relating to political activity; (ii) made any direct or indirect bribe, kickback, improper rebate, payoff, influence payment, or otherwise unlawfully provided anything of value, to any "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (collectively, the "FCPA")) or domestic government official; or (iii) violated or is in violation of any applicable provision of the FCPA, the Bribery Act 2010 of the United Kingdom, as amended (the "Bribery Act 2010"), or any other applicable anti-corruption or anti-bribery statute or regulation. The Company and, to the knowledge of the Company, the Company's controlled affiliates, have conducted their respective businesses in compliance with the FCPA, Bribery Act 2010 and all other applicable anti-corruption and anti-bribery statutes or regulations, and will institute and maintain policies and procedures designed to ensure, and which are reasonably expected to ensure, continued compliance therewith.
- (xx) The operations of the Company are and have been conducted at all times in all material respects in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of the jurisdictions where the Company conducts its business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, that have been issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator or non-governmental authority involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (yy) Neither the Company nor any of the Company's directors or officers, nor, to the knowledge of the Company, any agents employees or controlled affiliates of the Company is: (i) currently the subject or the target of any sanctions administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department, the U.S. Department of State, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"); or (ii) located, organized or resident in a country or territory that is the subject or target of Sanctions (including, without limitation, Cuba, Iran, North Korea, Syria and Crimea) ("Sanctioned Country"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing or facilitating the activities of any person, or in any country or territory, that at the time of such financing or facilitation is the subject or target of Sanctions or a Sanctioned Country, respectively, or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as an underwriter, advisor, investor or otherwise) of Sanctions. The Company has not knowingly engaged in for the past five years, is not now knowingly engaged in, and will not engage in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction, is or was the subject or target of Sanctions or a Sanctioned Country, respectively.

- The Company is not and has not, during the past three (3) years been, in violation of any Health Care Laws, except where the failure to be in compliance would not, individually or in the aggregate, result in a Material Adverse Effect. For purposes of this Agreement, "Health Care Laws" means (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et Seq.), and the regulations promulgated thereunder, (ii) the Public Health Service Act (42 U.S.C. §§ 201 et seq.) and the regulations promulgated thereunder, (iii) all federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. §1320a7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code, all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1035, 1347 and 1349, the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), and the regulations promulgated pursuant to such statutes, (iv) the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. §§669, 1035, 1347 and 1518; 42 U.S.C. §1320d et seq.) and the regulations promulgated thereunder, (v) Titles XVIII (42 U.S.C. §1395 et seq.) and XIX (42 U.S.C. §1396 et seq.) of the Social Security Act and the regulations promulgated thereunder, (vi) the Patient Protection and Affordable Care Act, (vii) all applicable statutes, rules or regulations relating to the ownership, testing, development, manufacture, quality, safety, accreditation, packaging, use, distribution, labeling, promotion, sale, offer for sale, import, export or disposal of any product manufactured or distributed by the Company, each of (i) through (vi) as may be amended from time to time. Neither the Company nor any of its officers, directors, employees, or, to the Company's knowledge, its agents, has been or is currently excluded from participation in the Medicare and Medicaid programs or any other state or federal health care program. The Company is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred or non-prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental authority.
- The Company has operated its businesses, and its businesses currently are, in compliance in all material respects with all applicable rules, regulations and policies of the FDA and any applicable foreign regulatory authority or organization. The Company: (i) has not, during the past three (3) years, received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other written correspondence or written notice from the U.S. Food and Drug Administration (the "FDA") or any other similar federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Health Care Laws (defined above) or any licenses, certificates, approvals, clearances, authorizations, exemptions, permits and supplements or amendments thereto required by any Health Care Laws to conduct the Company's business as described in the Pricing Disclosure Package ("Authorizations"); (ii) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company is not in material violation of any such Authorizations; (iii) has not received written notice of any pending or completed claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product candidate, operation or activity is in material violation of any Health Care Laws or material Authorizations and the Company has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (iv) has not received written notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, materially modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; and (v) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Authorizations and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission).

- (bbb) The description of the results of the studies, tests and trials contained in the Pricing Disclosure Package are accurate in all material respects and the Company has no knowledge of any other studies, tests or trials, the results of which are materially inconsistent with or would reasonably be expected to call into question in any material respect the results described in the Pricing Disclosure Package
- (ccc) Any clinical trials or human and animal studies described in the Pricing Disclosure Package were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and all applicable statutory requirements, rules, regulations and policies of the FDA, including current good clinical practices and Good Laboratory Practices as such terms are understood in the Company's including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, and 312, and all applicable foreign regulatory requirements and standards. Expect as disclosed in the Pricing Disclosure Package, the Company has not received any notices or correspondence from the FDA or any other governmental authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.
- To the Company's knowledge, the Company owns or possesses, or can acquire on reasonable terms, all material patents, patent rights, licenses, inventions, copyrights, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names and other intellectual property (collectively, "Intellectual Property") currently employed and proposed to be employed by it in connection with its businesses as now conducted and as described in the Pricing Disclosure Package, and the Company has not knowingly breached any material provision of any Intellectual Property license or received any notice of infringement of or conflict with asserted rights of others with respect to any of the foregoing which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, there are no valid and enforceable rights of third parties to any Intellectual Property that are or would be infringed in any material respect by the business currently conducted or planned to be conducted by the Company or in the manufacture, use, sale or offer for sale of its presently proposed products, as such planned business and proposed products are described in the Pricing Disclosure Package. There are no pending patent applications of which the Company is aware, which, if granted in current form, would be infringed in any material respect by the business currently conducted by it or proposed to be conducted by it as described in the Pricing Disclosure Package. The Company is not subject to any judgment, order, writ, injunction or decree of any court or any federal, state, local, foreign or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, or any arbitrator, nor has it entered into or is it a party to any contract, which materially restricts or impairs its use of any Intellectual Property. To the knowledge of the Company, there are no ongoing material infringements by others of any Intellectual Property owned by the Company in connection with the business currently conducted by the Company or its presently proposed products, except as described in the Pricing Disclosure Package.

- (eee) The Company's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") are adequate for, and Company has taken technical and organizational measures reasonably designed to protect information technology and Personal Data (as defined below) used in connection with, the operation of the business of the Company as currently conducted and as described in the Pricing Disclosure Package, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company has implemented and maintained reasonable controls, policies, procedures and safeguards designed to maintain and protect its confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including any personal, personally identifiable, household, sensitive, confidential or regulated data ("Personal Data")) used in connection with its business, except to the extent that a failure to do so could not reasonably be expected to have a Material Adverse Effect, and, to the knowledge of the Company, there have been no breaches, violations, outages or unauthorized uses of or accesses to any IT System or Personal Data used in connection with the operation of the Company's business. The Company is, and since October 1, 2017 has been, in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.
- (fff) The Company is, and since October 1, 2017 has been, in compliance with all applicable data privacy and security laws, statutes, judgements, orders, rules and regulations of any court or arbitrator or any other governmental or regulatory authority and all applicable laws regarding the collection, use, transfer, export, storage, protection, disposal or disclosure by the Company of Personal Data collected from or provided by third parties (collectively, the "*Privacy Laws*"), except where the failure to be in compliance would not, individually or in the aggregate, result in a Material Adverse Effect. The Company has in place, materially complies with, and takes appropriate steps reasonably designed to (i) ensure compliance with its privacy policies and all third-party contractual obligations regarding Personal Data; and (ii) reasonably protect the security and confidentiality of all Personal Data (collectively, the "*Policies*"). Since October 1, 2017, the Company has provided notice of its privacy policy on its corporate website, which provides accurate and sufficient notice of Company's then-current privacy practices relating to its subject matter. None of such disclosures made or contained in the privacy policies have been deceptive or in violation of any Privacy Laws or Policies in any material respect. To the knowledge of the Company, the execution, delivery and performance of this Agreement or any other agreement referred to in this Agreement will not result in a breach of violation of any Privacy Laws or Policies. The Company has not received written notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws and is unaware of any other facts that, individually or in the aggregate, would reasonably indicate non-compliance with any Privacy Laws or Policies. To the Company's knowledge, there is no action, suit or proceeding by or before any court or governmental agency, authority or body pending or threatened alleging non-compliance with

- (ggg) No forward looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) included in any of the Registration Statement, the Pricing Disclosure Package, the Prospectus or any "road show" (as defined in Rule 433 under the Securities Act) has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.
- (hhh) There are no affiliations or associations between (i) any member of FINRA and (ii) the Company or, to the Company's knowledge, any of the Company's officers, directors or 5% or greater security holders or any beneficial owner of the Company's unregistered equity securities that were acquired at any time on or after the 180th day immediately preceding the date the Registration Statement was initially filed with the Commission, except as disclosed in the Registration Statement (excluding the exhibits thereto), the Pricing Disclosure Package and the Prospectus or as otherwise disclosed to the Underwriters.

Any certificate signed by any officer of the Company and delivered to the Representative or counsel for the Underwriters in connection with the offering of the Stock shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase of the Stock by the Underwriters. On the basis of the representations, warranties and covenants contained in, and subject to the terms and conditions of, this Agreement, the Company agrees to sell [•] shares of the Firm Stock to the several Underwriters, and each of the Underwriters, severally and not jointly, agrees to purchase the number of shares of the Firm Stock set forth opposite that Underwriter's name in Schedule I hereto. The respective purchase obligations of the Underwriters with respect to the Firm Stock shall be rounded among the Underwriters to avoid fractional shares, as the Representative may determine.

In addition, the Company grants to the Underwriters an option to purchase up to [•] additional shares of Option Stock. Each Underwriter agrees, severally and not jointly, to purchase the number of shares of Option Stock (subject to such adjustments to eliminate fractional shares as the Representative may determine) that bears the same proportion to the total number of shares of Option Stock to be sold on such Delivery Date as the number of shares of Firm Stock set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of shares of Firm Stock.

The purchase price payable by the Underwriters for both the Firm Stock and any Option Stock is \$[●] per share.

The Company is not obligated to deliver any of the Firm Stock or Option Stock to be delivered on the applicable Delivery Date, except upon payment for all such Stock to be purchased on such Delivery Date as provided herein.

- 3. *Offering of Stock by the Underwriters*. Upon authorization by the Representative of the release of the Firm Stock, the several Underwriters propose to offer the Firm Stock for sale upon the terms and conditions to be set forth in the Prospectus.
- 4. Delivery of and Payment for the Stock. Delivery of and payment for the Firm Stock shall be made at 10:00 A.M., New York City time, on [·], 2021, or at such other date or place as shall be determined by agreement between the Representative and the Company. This date and time are sometimes referred to as the "Initial Delivery Date". Delivery of the Firm Stock shall be made to the Representative for the account of each Underwriter against payment by the several Underwriters through the Representative and of the respective aggregate purchase prices of the Firm Stock being sold by the Company to or upon the order of the Company of the purchase price by wire transfer in immediately available funds to the accounts specified by the Company. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. The Company shall deliver the Firm Stock through the facilities of The Depository Trust Company ("DTC") unless the Representative shall otherwise instruct.

The option granted in Section 2 will expire 30 days after the date of this Agreement and may be exercised in whole or from time to time in part by written notice being given to the Company by the Representative; *provided* that if such date falls on a day that is not a business day, the option granted in Section 2 will expire on the next succeeding business day. Such notice shall set forth the aggregate number of shares of Option Stock as to which the option is being exercised, the names in which the shares of Option Stock are to be registered, the denominations in which the shares of Option Stock are to be issued and the date and time, as determined by the Representative, when the shares of Option Stock are to be delivered; *provided*, *however*, that this date and time shall not be earlier than the Initial Delivery Date nor earlier than the second business day after the date on which the option shall have been exercised nor later than the fifth business day after the date on which the option shall have been exercised. Each date and time the shares of Option Stock are delivered is sometimes referred to as an "Option Stock Delivery Date", and the Initial Delivery Date and any Option Stock Delivery Date are sometimes each referred to as a "Delivery Date".

Delivery of the Option Stock by the Company and payment for the Option Stock by the several Underwriters through the Representative shall be made at 10:00 A.M., New York City time, on the date specified in the corresponding notice described in the preceding paragraph or at such other date or place as shall be determined by agreement between the Representative and the Company. On each Option Stock Delivery Date, the Company shall deliver, or cause to be delivered, the Option Stock, to the Representative for the account of each Underwriter, against payment by the several Underwriters through the Representative and of the respective aggregate purchase prices of the Option Stock being sold by the Company to or upon the order of the Company of the purchase price by wire transfer in immediately available funds to the accounts specified by the Company. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. The Company shall deliver the Option Stock through the facilities of DTC unless the Representative shall otherwise instruct.

- 5. Further Agreements of the Company and the Underwriters. (a) The Company agrees:
- (i) To prepare the Prospectus in a form approved by the Representative and to file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement; to make no further amendment or any supplement to the Registration Statement or the Prospectus prior to the last Delivery Date except as provided herein; to advise the Representative, promptly after it receives notice thereof, of the time when any amendment or supplement to the Registration Statement or the Prospectus has been filed and to furnish the Representative with copies thereof; to advise the Representative, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus, of the suspension of the qualification of the Stock for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding or examination for any such purpose, or any notice from the Commission objecting to the use of the form of Registration Statement or any post-effective amendment thereto or of any request by the Commission for the amending or supplementing of the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus or suspending any such qualification, to use promptly its best efforts to obtain its withdrawal.
- (ii) To furnish promptly to each of the Representative and to counsel for the Underwriters a signed copy of the Registration Statement as originally filed with the Commission, and each amendment thereto filed with the Commission, including all consents and exhibits filed therewith.

- (iii) To deliver, upon request, promptly to the Representative such number of the following documents as the Representative shall reasonably request: (A) conformed copies of the Registration Statement as originally filed with the Commission and each amendment thereto (in each case excluding exhibits other than this Agreement and the computation of per share earnings), (B) each Preliminary Prospectus, the Prospectus and any amended or supplemented Prospectus, and (C) each Issuer Free Writing Prospectus; and, if the delivery of a prospectus is required at any time after the date hereof in connection with the offering or sale of the Stock or any other securities relating thereto and if at such time any events shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it shall be necessary to amend or supplement the Prospectus in order to comply with the Securities Act, to notify the Representative and, upon their request, to file such document and to prepare and furnish without charge to each Underwriter and to any dealer in securities as many copies as the Representative may from time to time reasonably request of an amended or supplemented Prospectus that will correct such statement or omission or effect such compliance.
- (iv) To file promptly with the Commission any amendment or supplement to the Registration Statement or the Prospectus that may, in the judgment of the Company and the Representative, be required by the Securities Act or requested by the Commission.
- (v) Prior to filing with the Commission any amendment or supplement to the Registration Statement, or the Prospectus, to furnish a copy thereof to the Representative and counsel for the Underwriters and obtain the consent of the Representative to the filing, which consent shall not be unreasonably withheld.
- (vi) Not to make any offer relating to the Stock that would constitute an Issuer Free Writing Prospectus without the prior written consent of the Representative.
- (vii) To comply with all applicable requirements of Rule 433 under the Securities Act with respect to any Issuer Free Writing Prospectus. If at any time after the date hereof any events shall have occurred as a result of which any Issuer Free Writing Prospectus, as then amended or supplemented, would conflict with the information in the Registration Statement, the Pricing Disclosure Package or the Prospectus or would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or, if for any other reason it shall be necessary to amend or supplement any Issuer Free Writing Prospectus, to notify the Representative and, upon their request, to file such document and to prepare and furnish without charge to each Underwriter as many copies as the Representative may from time to time reasonably request of an amended or supplemented Issuer Free Writing Prospectus that will correct such conflict, statement or omission or effect such compliance.

- (viii) As soon as practicable after the Effective Date (it being understood that the Company shall have until at least 410 days or, if the fourth quarter following the fiscal quarter that includes the Effective Date is the last fiscal quarter of the Company's fiscal year, 455 days after the end of the Company's current fiscal quarter), to make generally available to the Company's security holders and to deliver to the Representative an earnings statement of the Company (which need not be audited) complying with Section 11(a) of the Securities Act and the rules and regulations thereunder (including, at the option of the Company, Rule 158).
- (ix) Promptly from time to time to take such action as the Representative may reasonably request to qualify the Stock for offering and sale under the securities or Blue Sky laws of Canada and such other jurisdictions as the Representative may reasonably request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the distribution of the Stock; *provided*, that in connection therewith the Company shall not be required to (A) qualify as a foreign corporation in any jurisdiction in which it would not otherwise be required to so qualify, (B) file a general consent to service of process in any such jurisdiction, or (C) subject itself to taxation in any jurisdiction in which it would not otherwise be subject.
- For a period commencing on the date hereof and ending on the 180th day after the date of the Prospectus (the "Lock-Up Period"), not to, directly or indirectly, (A) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock (other than the Stock and shares issued pursuant to employee benefit plans, qualified stock option plans, other employee compensation plans or other plan or arrangements of the Company described in the most recent Preliminary Prospectus (the "Company Plans"), or pursuant to currently outstanding warrants not issued under one of those plans), or sell or grant options, rights or warrants with respect to any shares of Common Stock or securities convertible into or exchangeable for Common Stock (other than the grant of options pursuant to Company Plans), (B) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of such shares of Common Stock, whether any such transaction described in clause (A) or (B) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, (C) file, confidentially submit or cause to be confidentially submitted or filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Common Stock or securities convertible, exercisable or exchangeable into Common Stock or any other securities of the Company, or (D) publicly disclose the intention to do any of the foregoing, in each case without the prior written consent of B. Riley Securities, Inc., on behalf of the Underwriters, and to cause each officer, director and securityholders of the Company to furnish to the Representative, prior to the Initial Delivery Date, a letter or letters, substantially in the form of Exhibit A hereto (the "Lock-Up Agreements"); provided however, that the Company may: (i) file one or more registration statements on Form S-8 relating to any Company Plan, (ii) shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for shares of Common Stock in connection with the acquisition or license by the Company of the securities, business, property, technology or other assets of another person or business entity or pursuant to any employee benefit plan assumed by the Company in connection with any such acquisition; (iii) issue shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for shares of Common Stock, or enter into an agreement to issue shares of Common Stock, or any securities convertible into or exercisable or exchangeable for shares of Common Stock in connection with any merger, joint venture, strategic alliance or partnership) as long as, with respect to (ii) and (iii), (x) the aggregate number of shares of Common Stock, or securities convertible into or exercisable or exchangeable for shares of Common Stock, that the Company may issue or agree to issue, shall not exceed 5% of the total outstanding shares of Common Stock immediately following the issuance of the Stock, and (y) the recipients of such securities provide to the Representative a signed Lock-Up Agreement and (iv) assist any stockholder of the Company in the establishment of a trading plan by such stockholder pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, provided that such plan does not provide for the transfer or any sale of shares of Common Stock during the Lock-Up Period, and the establishment of such plan does not require or otherwise result in any public filings or other public announcement of such plan during such Lock-Up Period and such plan is otherwise permitted to be implemented during the Lock-Up Period pursuant to the terms of the Lock-Up Agreement between such stockholder and the Underwriters in connection with the offering of the Stock.

- (xi) The Company will use its reasonable best efforts to enforce all existing agreements between the Company and any of its securityholders that prohibit the sale, transfer, assignment, pledge or hypothecation of any of the Company's securities in connection with the Company's initial public offering until, in respect of any particular securityholder, the earlier to occur of (i) the expiration of the Lock-Up Period or (ii) the expiration, which shall not be amended or otherwise modified, of any similar arrangement entered into by such securityholder with the Representative; to direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such existing "lock-up", "market stand-off", "holdback" or similar provisions of such agreements for the duration of the periods contemplated in the preceding clause; and not to release or otherwise grant any waiver of such provisions in such agreements during such periods without the prior written consent of the Representative, on behalf of the Underwriters.
- (xii) If the Representative, in its sole discretion, agrees to release or waive the restrictions set forth in a Lock-Up Agreement for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver in accordance with FINRA Rule 5131 (which may include by issuing a press release substantially in the form of Exhibit B hereto), and containing such other information as the Representative may require with respect to the circumstances of the release or waiver and/or the identity of the officer(s) and/or director(s) with respect to which the release or waiver applies, in accordance with FINRA Rule 5131.

- (xiii) To apply the net proceeds from the sale of the Stock being sold by the Company substantially in accordance with the description as set forth in the Prospectus under the caption "Use of Proceeds."
- (xiv) To file with the Commission such information on Form 10-Q or Form 10-K as may be required by Rule 463 under the Securities Act.
- (xv) If the Company elects to rely upon Rule 462(b) under the Securities Act, the Company shall file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) under the Securities Act by 10:00 P.M., Washington, D.C. time, on the date of this Agreement, and the Company shall at the time of filing pay the Commission the filing fee for the Rule 462(b) Registration Statement.
- (xvi) The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (A) the time when a prospectus relating to the offering or sale of the Stock or any other securities relating thereto is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (B) completion of the Lock-Up Period.
- (xvii) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission. The Company will promptly notify the Representative of (A) any distribution by the Company of Written Testing-the-Waters Communications and (B) any request by the Commission for information concerning the Written Testing-the-Waters Communications.
- (xviii) The Company will not take, and will use its reasonable best efforts to ensure that its affiliates do not take, directly or indirectly, any action designed to or that has constituted or that reasonably would be expected to cause or result in the stabilization or manipulation of the price of any security of the Company in connection with the offering of the Stock.
- (xix) The Company will do and perform all things required or necessary to be done and performed under this Agreement by it prior to each Delivery Date, and to satisfy all conditions precedent to the Underwriters' obligations hereunder to purchase the Stock.
- (xx) The Company will deliver to each Underwriter (or its agent) pursuant to a written request, on or prior to the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers or applicable exemption certificate (the "FinCEN Certification"), together with copies of identifying documentation, of the Company and the Company undertakes to provide such additional supporting documentation as each Underwriter may reasonably request in connection with the verification of the FinCEN Certification.

- (b) Each Underwriter severally agrees that such Underwriter shall not include any "issuer information" (as defined in Rule 433 under the Securities Act) in any "free writing prospectus" (as defined in Rule 405 under the Securities Act) used or referred to by such Underwriter without the prior consent of the Company (any such issuer information with respect to whose use the Company has given its consent, "*Permitted Issuer Information*"); provided that (i) no such consent shall be required with respect to any such issuer information contained in any document filed by the Company with the Commission prior to the use of such free writing prospectus, and (ii) "issuer information", as used in this Section 5(b), shall not be deemed to include information prepared by or on behalf of such Underwriter on the basis of or derived from issuer information.
- Expenses. The Company agrees, whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, to pay all expenses, costs, fees and taxes incident to and in connection with (a) the authorization, issuance, sale and delivery of the Stock and any stamp duties or other taxes payable in that connection, and the preparation and printing of certificates for the Stock; (b) the preparation, printing and filing under the Securities Act of the Registration Statement (including any exhibits thereto), any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, and any amendment or supplement thereto; (c) the distribution of the Registration Statement (including any exhibits thereto), any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, and any amendment or supplement thereto, all as provided in this Agreement; (d) the production and distribution of this Agreement, any supplemental agreement among Underwriters, and any other related documents in connection with the offering, purchase, sale and delivery of the Stock; (f) any required review by the FINRA of the terms of sale of the Stock (including related fees and expenses of counsel to the Underwriters); (g) the listing of the Stock on The Nasdaq Global Market and/or any other exchange; (h) the qualification of the Stock under the securities laws of the several jurisdictions as provided in Section 5(a)(ix) and the preparation, printing and distribution of a Blue Sky Memorandum (including related fees and expenses of counsel to the Underwriters); (i) the preparation, printing and distribution of one or more versions of the Preliminary Prospectus and the Prospectus for distribution in Canada, including in the form of a Canadian "wrapper" (including related fees and expenses of Canadian counsel to the Underwriters) (j) the investor presentations on any "road show" or any Testing-the-Waters Communication, undertaken in connection with the marketing of the Stock, including, without limitation, expenses associated with any electronic road show, travel and lodging expenses of the representatives and officers of the Company and 50% of the cost of any aircraft that is used to transport representatives from both the Company and the Underwriters in connection with the road show (with the other 50% being paid by the Underwriters); and (k) all other costs and expenses incident to the performance of the obligations of the Company under this Agreement; provided that, except as provided in this Section 6 and in Section 11, the Underwriters shall pay their own costs and expenses, including the costs and expenses of their counsel, any transfer taxes on the Stock which they may sell and the expenses of advertising any offering of the Stock made by the Underwriters. Notwithstanding the preceding sentence, the Company agrees to reimburse the Representative, upon request, for any fees and disbursements of legal counsel to the Underwriters in an amount not to exceed \$850,000, provided that any amounts the Company pays in respect of counsel fees and expenses pursuant to clauses (f), (h) or (i) of the preceding sentence shall be deemed to have been reimbursed pursuant to this sentence.

- 7. *Conditions of Underwriters' Obligations*. The respective obligations of the Underwriters hereunder are subject to the accuracy, when made and on each Delivery Date, of the representations and warranties of the Company contained herein, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:
  - (a) The Prospectus shall have been timely filed with the Commission in accordance with Section 5(a)(i). The Company shall have complied with all filing requirements applicable to any Issuer Free Writing Prospectus used or referred to after the date hereof; no stop order suspending the effectiveness of the Registration Statement or preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus shall have been issued and no proceeding or examination for such purpose shall have been initiated or threatened by the Commission; and any request of the Commission for inclusion of additional information in the Registration Statement or the Prospectus or otherwise shall have been complied with. If the Company has elected to rely upon Rule 462(b) under the Securities Act, the Rule 462(b) Registration Statement shall have become effective by 10:00 P.M., Washington, D.C. time, on or before the date of this Agreement.
  - (b) All corporate proceedings and other legal matters incident to the authorization, form and validity of this Agreement, the Stock, the Registration Statement, the Prospectus and any Issuer Free Writing Prospectus, and all other legal matters relating to this Agreement and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.
  - (c) Cooley LLP shall have furnished to the Representative its written opinion, as counsel to the Company, addressed to the Underwriters and dated such Delivery Date, in form and substance reasonably satisfactory to the Representative.
  - (d) Elmore Patent Law Group, PC shall have furnished to the Representative its written opinion, as intellectual property counsel to the Company, addressed to the Underwriters and dated such Delivery Date, in form and substance reasonably satisfactory to the Representative.
  - (e) The Representative shall have received from Latham & Watkins LLP, counsel for the Underwriters, such opinion and negative assurance letter, dated such Delivery Date, with respect to the issuance and sale of the Stock, the Registration Statement, the Prospectus and the Pricing Disclosure Package and other related matters as the Representative may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to pass upon such matters.

- (f) At the time of execution of this Agreement, the Representative shall have received from CohnReznick LLP a letter, in form and substance satisfactory to the Representative, addressed to the Underwriters and dated the date hereof (i) confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, and (ii) stating, as of the date hereof (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Pricing Disclosure Package, as of a date not more than three days prior to the date hereof), the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings.
- (g) With respect to the letter of CohnReznick LLP referred to in the preceding paragraph and delivered to the Representative concurrently with the execution of this Agreement (the "*initial letter*"), the Company shall have furnished to the Representative a letter (the "*bring-down letter*") of such accountants, addressed to the Underwriters and dated such Delivery Date (i) confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, (ii) stating, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Prospectus, as of a date not more than three days prior to the date of the bring-down letter), the conclusions and findings of such firm with respect to the financial information and other matters covered by the initial letter, and (iii) confirming in all material respects the conclusions and findings set forth in the initial letter.
- (h) The Company shall have furnished to the Representative a certificate, dated such Delivery Date, of its Chief Executive Officer as to such matters as the Representative may reasonably request, including, without limitation, a statement:
  - (i) That the representations, warranties and agreements of the Company in Section 1 are true and correct on and as of such Delivery Date, and the Company has complied with all its agreements contained herein and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such Delivery Date;
  - (ii) That no stop order suspending the effectiveness of the Registration Statement has been issued; and no proceedings or examination for that purpose have been instituted or, to the knowledge of such officers, threatened;

- (iii) That they have examined the Registration Statement, the Prospectus and the Pricing Disclosure Package, and, in their opinion, (A) (1) the Registration Statement, as of the Effective Date, (2) the Prospectus, as of its date and on the applicable Delivery Date, and (3) the Pricing Disclosure Package, as of the Applicable Time, did not and do not contain any untrue statement of a material fact and did not and do not omit to state a material fact required to be stated therein or necessary to make the statements therein (except in the case of the Registration Statement, in the light of the circumstances under which they were made) not misleading, and (B) since the Effective Date, no event has occurred that should have been set forth in a supplement or amendment to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus in order for such documents not to contain a material misstatement or omission that has not been so set forth; and
- (iv) To the effect of Section 7(i) (*provided* that no representation with respect to the judgment of the Representative need be made) and Section 7(j).
- The Company has not sustained, since the date of the latest audited financial statements included in the Pricing Disclosure Package and the Prospectus, any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, or (ii) since such date there shall not have been any change in the capital stock or long-term debt of the Company or any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), results of operations, stockholders' equity, properties, management, business or prospects of the Company taken as a whole, the effect of which, in any such case described in clause (i) or (ii), would not, individually or in the aggregate, in the judgment of the Representative, so material and adverse as to make it impracticable or inadvisable to proceed with the public offering or the delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.
- (k) Subsequent to the execution and delivery of this Agreement there shall not have occurred any of the following: (i) (A) trading in securities generally on any securities exchange that has registered with the Commission under Section 6 of the Exchange Act (including the New York Stock Exchange, The Nasdaq Global Select Market, The Nasdaq Global Market or The Nasdaq Capital Market), or (B) trading in any securities of the Company on any exchange or in the over-the-counter market, shall have been suspended or materially limited or the settlement of such trading generally shall have been materially disrupted or minimum prices shall have been established on any such exchange or such market by the Commission, by such exchange or by any other regulatory body or governmental authority having jurisdiction, (ii) a general moratorium on commercial banking activities shall have been declared by federal or state authorities, (iii) the United States shall have become engaged in hostilities, there shall have been an escalation in hostilities involving the United States or there shall have been a declaration of a national emergency or war by the United States, or (iv) there shall have occurred such a material adverse change in general economic, political or financial conditions, including, without limitation, as a result of terrorist activities after the date hereof (or the effect of international conditions on the financial markets in the United States shall be such) or any other calamity or crisis, either within or outside the United States, in each case as to make it, in the judgment of the Representative, impracticable or inadvisable to proceed with the public offering or delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.

- (l) The Nasdaq Global Market shall have approved the Stock for listing, subject only to official notice of issuance and evidence of satisfactory distribution.
- (m) The Lock-Up Agreements between the Representative and the officers, directors and substantially all securityholders of the Company, delivered to the Representative prior to the date of this Agreement, shall be in full force and effect on such Delivery Date.
- (n) On or prior to each Delivery Date, the Company shall have furnished to the Underwriters such further certificates and documents as the Representative may reasonably request.
- (o) FINRA shall not have raised any objection with respect to the fairness or reasonableness of the underwriting, or other arrangements of the transactions, contemplated hereby.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

### 8. Indemnification and Contribution.

(a) The Company hereby agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers and employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof (including, but not limited to, any loss, claim, damage, liability or action relating to purchases and sales of Stock), to which that Underwriter, affiliate, director, officer, employee or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in (A) any Preliminary Prospectus, the Registration Statement, the Prospectus or in any amendment or supplement thereto, (B) any Issuer Free Writing Prospectus or in any amendment or supplement thereto, (C) any Permitted Issuer Information used or referred to in any "free writing prospectus" (as defined in Rule 405 under the Securities Act) used or referred to by any Underwriter, (D) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Stock, including any "road show" (as defined in Rule 433 under the Securities Act) not constituting an Issuer Free Writing Prospectus and any Written Testing-the-Waters Communication ("Marketing Materials"), or (E) any Blue Sky application or other document prepared or executed by the Company (or based upon any written information furnished by the Company for use therein) specifically for the purpose of qualifying any or all of the Stock under the securities laws of any state or other jurisdiction (any such application, document or information being hereinafter called a "Blue Sky Application") or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Permitted Issuer Information, any Marketing Materials or any Blue Sky Application, any material fact required to be stated therein or necessary to make the statements therein not misleading, and shall reimburse each Underwriter and each such affiliate, director, officer, employee or controlling person promptly upon demand for any legal or other documented expenses reasonably incurred by that Underwriter, affiliate, director, officer, employee or controlling person in connection with investigating or defending or preparing to defend against any such loss, claim, damage, liability or action as such documented expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of, or is based upon, any untrue statement or alleged untrue statement or omission or alleged omission made in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any such amendment or supplement thereto or in any Permitted Issuer Information, any Marketing Materials or any Blue Sky Application, in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information consists solely of the information specified in Section 8(e). The foregoing indemnity agreement is in addition to any liability which the Company may otherwise have to any Underwriter or to any affiliate, director, officer, employee or controlling person of that Underwriter.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company, its directors (including any person who, with his or her consent, is named in the Registration Statement as about to become a director of the Company), officers and employees, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof, to which the Company or any such director, officer, employee or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials or Blue Sky Application, or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials or Blue Sky Application, any material fact required to be stated therein or necessary to make the statements therein not misleading, but in each case only to the extent that the untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representative by or on behalf of that Underwriter specifically for inclusion therein, which information is limited to the information set forth in Section 8(e). The foregoing indemnity agreement is in addition to any liability that any Underwriter may otherwise have to the Company or any such director, officer, employee or controlling person.

Promptly after receipt by an indemnified party under this Section 8 of notice of any claim or the commencement of any action, the indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the claim or the commencement of that action; provided, however, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have under this Section 8 except to the extent it has been materially prejudiced (through the forfeiture of substantive rights and defenses) by such failure and, provided, further, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have to an indemnified party otherwise than under this Section 10. If any such claim or action shall be brought against an indemnified party, and it shall notify the indemnifying party thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it wishes, jointly with any other similarly notified indemnifying party, to assume the defense thereof with counsel reasonably satisfactory to the indemnified party. After notice from the indemnifying party to the indemnified party of its election to assume the defense of such claim or action, the indemnifying party shall not be liable to the indemnified party under this Section 8 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that the indemnified party shall have the right to employ counsel to represent jointly the indemnified party and those other indemnified parties and their respective directors, officers, employees and controlling persons who may be subject to liability arising out of any claim in respect of which indemnity may be sought under this Section 8 if (i) the indemnified party and the indemnifying party shall have so mutually agreed; (ii) the indemnifying party has failed within a reasonable time to retain counsel reasonably satisfactory to the indemnified party; (iii) the indemnified party and its directors, officers, employees and controlling persons shall have reasonably concluded that there may be legal defenses available to them that are different from or in addition to those available to the indemnifying party; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the indemnified parties or their respective directors, officers, employees or controlling persons, on the one hand, and the indemnifying party, on the other hand, and representation of both sets of parties by the same counsel would be inappropriate due to actual or potential differing interests between them, and in any such event the fees and expenses of such separate counsel shall be paid by the indemnifying party. No indemnifying party shall (x) without the prior written consent of the indemnified parties (which consent shall not be unreasonably withheld), settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and does not include a statement as to, or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party, or (y) be liable for any settlement of any such action effected without its written consent (which consent shall not be unreasonably withheld), but if settled with the consent of the indemnifying party or if there be a final judgment for the plaintiff in any such action, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 8(a) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request or disputed in good faith the indemnified party's entitlement to such reimbursement prior to the date of such settlement.

If the indemnification provided for in this Section 8 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 8(a) or 8(b) in respect of any loss, claim, damage or liability, or any action in respect thereof, referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Stock, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, with respect to the statements or omissions that resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, with respect to such offering shall be deemed to be in the same proportion as the total net proceeds from the offering of the Stock purchased under this Agreement (before deducting expenses) received by the Company, as set forth in the table on the cover page of the Prospectus, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Stock purchased under this Agreement, as set forth in the table on the cover page of the Prospectus, on the other hand. The relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 8(d) were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section 8(d) shall be deemed to include, for purposes of this Section 8(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8(d), in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Stock exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute as provided in this Section 8(d) are several in proportion to their respective underwriting obligations and not joint.

(e) The Underwriters severally confirm and the Company acknowledges and agrees that the statements regarding delivery of shares by the Underwriters set forth on the cover page of, and the concession and reallowance figures and the paragraph relating to stabilization by the Underwriters appearing under the caption "Underwriting" in, the Pricing Disclosure Package and the Prospectus are correct and constitute the only information concerning such Underwriters furnished in writing to the Company by or on behalf of the Underwriters specifically for inclusion in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials.

### 9. Defaulting Underwriters.

If, on any Delivery Date, any Underwriter defaults in its obligations to purchase the Stock that it has agreed to purchase under this Agreement, the remaining non-defaulting Underwriters may in their discretion arrange for the purchase of such Stock by the non-defaulting Underwriters or other persons satisfactory to the Company on the terms contained in this Agreement. If, within 36 hours after any such default by any Underwriter, the non-defaulting Underwriters do not arrange for the purchase of such Stock, then the Company shall be entitled to a further period of 36 hours within which to procure other persons satisfactory to the non-defaulting Underwriters to purchase such Stock on such terms. In the event that within the respective prescribed periods, the non-defaulting Underwriters notify the Company that they have so arranged for the purchase of such Stock, or the Company notifies the non-defaulting Underwriters that it has so arranged for the purchase of such Stock, either the non-defaulting Underwriters or the Company may postpone such Delivery Date for up to seven full business days in order to effect any changes that in the opinion of counsel for the Company or counsel for the Underwriters may be necessary in the Registration Statement, the Prospectus or in any other document or arrangement, and the Company agrees to promptly prepare any amendment or supplement to the Registration Statement, the Prospectus or in any such other document or arrangement that effects any such changes. As used in this Agreement, the term "Underwriter," unless the context requires otherwise, includes any party not listed in Schedule I hereto that, pursuant to this Section 9, purchases Stock that a defaulting Underwriter agreed but failed to purchase.

- (b) If, after giving effect to any arrangements for the purchase of the Stock of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the total number of shares of the Stock that remains unpurchased does not exceed one-eleventh of the total number of shares of all the Stock, then the Company shall have the right to require each non-defaulting Underwriter to purchase the total number of shares of Stock that such Underwriter agreed to purchase hereunder plus such Underwriter's pro rata share (based on the total number of shares of Stock that such Underwriter agreed to purchase hereunder) of the Stock of such defaulting Underwriter or Underwriters for which such arrangements have not been made; provided that the non-defaulting Underwriters shall not be obligated to purchase more than 110% of the total number of shares of Stock that it agreed to purchase on such Delivery Date pursuant to the terms of Section 2.
- (c) If, after giving effect to any arrangements for the purchase of the Stock of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the total number of shares of Stock that remains unpurchased exceeds one-eleventh of the total number of shares of all the Stock, or if the Company shall not exercise the right described in paragraph (b) above, then this Agreement shall terminate without liability on the part of the non-defaulting Underwriters. Any termination of this Agreement pursuant to this Section 9 shall be without liability on the part of the Company, except that the Company will continue to be liable for the payment of expenses as set forth in Sections 8 and 13 and except that the provisions of Section 8 shall not terminate and shall remain in effect.
- (d) Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company or any non-defaulting Underwriter for damages caused by its default.
- 10. *Termination*. The obligations of the Underwriters hereunder may be terminated by the Representative by notice given to and received by the Company prior to delivery of and payment for the Firm Stock if, prior to that time, any of the events described in Sections 7(j), 7(k) and 7(l) shall have occurred or if the Underwriters shall decline to purchase the Stock for any reason permitted under this Agreement.
- 11. Reimbursement of Underwriters' Expenses. If (a) the Company shall fail to tender the Stock for delivery to the Underwriters for any reason, or (b) the Underwriters shall decline to purchase the Stock for any reason permitted under this Agreement, the Company will reimburse the Underwriters for all reasonable and documented out-of-pocket expenses (including fees and disbursements of counsel for the Underwriters) incurred by the Underwriters in connection with this Agreement and the proposed purchase of the Stock, and upon demand the Company shall pay the full amount thereof to the Representative. If this Agreement is terminated pursuant to Section 9 by reason of the default of one or more Underwriters, the Company shall not be obligated to reimburse any defaulting Underwriter on account of those expenses.

- 12. Research Analyst Independence. The Company acknowledges that the Underwriters' research analysts and research departments are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriters' research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of their respective investment banking divisions. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriters' investment banking divisions. The Company acknowledges that each of the Underwriters is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.
- 13. *No Fiduciary Duty*. The Company acknowledges and agrees that in connection with this offering, sale of the Stock or any other services the Underwriters may be deemed to be providing hereunder, notwithstanding any preexisting relationship, advisory or otherwise, between the parties or any oral representations or assurances previously or subsequently made by the Underwriters: (a) no fiduciary or agency relationship between the Company and any other person, on the one hand, and the Underwriters, on the other hand, exists; (b) the Underwriters are not acting as advisors, expert or otherwise and are not providing a recommendation or investment advice, to the Company, including, without limitation, with respect to the determination of the public offering price of the Stock, and such relationship between the Company, on the one hand, and the Underwriters, on the other hand, is entirely and solely commercial, based on arms-length negotiations and, as such, not intended for use by any individual for personal, family or household purposes; (c) any duties and obligations that the Underwriters may have to the Company shall be limited to those duties and obligations specifically stated herein; (d) the Underwriters and their respective affiliates may have interests that differ from those of the Company; and (e) does not constitute a solicitation of any action by the Underwriters with respect to any breach of fiduciary duty in connection with this offering and (y) agrees that none of the activities of the Underwriters with respect to any entity or natural person. The Company has consulted its own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate.
  - 14. Notices, etc. All statements, requests, notices and agreements hereunder shall be in writing, and:
  - (a) if to the Underwriters, shall be delivered or sent by mail or facsimile transmission to B. Riley Securities, Inc., 299 Park Avenue, New York, NY 10171, Attention: Syndicate Department; and

(b) if to the Company, shall be delivered or sent by mail or facsimile transmission to the address of the Company set forth on the cover page of the Registration Statement, Attention: William Ho, with a copy to Cooley LLP, 55 Hudson Yards, New York, New York 10001, Attention: Joshua Kaufman.

Any such statements, requests, notices or agreements shall take effect at the time of receipt thereof. The Company shall be entitled to act and rely upon any request, consent, notice or agreement given or made on behalf of the Underwriters by B. Riley Securities, Inc.

- 15. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the Underwriters, the Company, and their respective successors. This Agreement and the terms and provisions hereof are for the sole benefit of only those persons, except that (a) the representations, warranties, indemnities and agreements of the Company contained in this Agreement shall also be deemed to be for the benefit of the directors, officers and employees of the Underwriters and each person or persons, if any, who control any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, and (b) the indemnity agreement of the Underwriters contained in Section 8(b) of this Agreement shall be deemed to be for the benefit of the directors of the Company, the officers of the Company who have signed the Registration Statement and any person controlling the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act. Nothing in this Agreement is intended or shall be construed to give any person, other than the persons referred to in this Section 17, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein.
- 16. *Survival*. The respective indemnities, rights of contributions, representations, warranties and agreements of the Company and the Underwriters contained in this Agreement or made by or on behalf of them, respectively, pursuant to this Agreement, shall survive the delivery of and payment for the Stock and shall remain in full force and effect, regardless of any investigation made by or on behalf of any of them or any person controlling any of them.
- 17. *Definition of the Terms "Business Day" and "Affiliate"*. For purposes of this Agreement, (a) "*business day*" means each Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in New York are generally authorized or obligated by law or executive order to close, and (b) "*affiliate*" has the meanings set forth in Rule 405 under the Securities Act.
- 18. *Governing Law*. This Agreement and any transaction contemplated by this Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to conflict of laws principles that would result in the application of any other law than the laws of the State of New York (other than Section 5-1401 of the General Obligations Law).
- 19. *Waiver of Jury Trial*. The Company and the Underwriters hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

- 20. *Counterparts*. This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original but all such counterparts shall together constitute one and the same instrument.
- 21. *Headings*. The headings herein are inserted for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.
  - 22. Recognition of the U.S. Special Resolution Regimes.
  - (a) In the event that any of the Underwriters that are a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
  - (b) In the event that any of the Underwriters that are a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For the purposes of this Section 15, a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). " "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

If the foregoing correctly sets forth the agreement between the Company at that purpose below.	and the Underwriters, please indicate your acceptance in the space provided for
	Very truly yours,
	IN8BIO, INC.
	Ву:
	Name: William Ho Title: President and Chief Executive Officer

Accepted:			
B. Riley Securities, Inc	2		
For itself and as Repre of the several Underwi in Schedule I hereto			
By: B. Riley Securit	ies, Inc.		
By: Name: Title:		_	

# SCHEDULE I

	Number of	Number of
	Shares of	Shares of
Underwriters	Firm Stock	Option Stock
B. Riley Securities, Inc.	[•]	[•]
Total	[•]	[•]

### SCHEDULE II

### ORALLY CONVEYED PRICING INFORMATION

- 1. Public offering price here:  $\{[ullet]$
- 2. Number of Firm Shares offered: [ullet]
- 3. Number of Option Shares offered: [ullet]

# SCHEDULE III

ISSUER FREE WRITING PROSPECTUSES – ROAD SHOW MATERIALS

# SCHEDULE IV

ISSUER FREE WRITING PROSPECTUS

# SCHEDULE V

WRITTEN TESTING-THE-WATERS COMMUNICATIONS

#### **EXHIBIT A**

#### LOCK-UP LETTER AGREEMENT

B. Riley Securities, Inc.

As Representative of the several

Underwriters.

c/o B. Riley Securities, Inc. 745 299 Park Avenue New York, New York 10171

Ladies and Gentlemen:

The undersigned understands that you and certain other firms (the "*Underwriters*") propose to enter into an Underwriting Agreement (the "*Underwriting Agreement*") providing for the purchase by the Underwriters of shares (the "*Stock*") of Common Stock, par value \$0.0001 per share (the "*Common Stock*"), of IN8bio, Inc., a Delaware corporation (the "*Company*"), and that the Underwriters propose to reoffer the Stock to the public (the "*Offering*"). Capitalized terms used but not defined herein shall have the respective meanings ascribed to such terms in the Underwriting Agreement.

In consideration of the execution of the Underwriting Agreement by the Underwriters, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby irrevocably agrees that, without the prior written consent of B. Riley Securities, Inc., on behalf of the Underwriters, the undersigned will not, directly or indirectly, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock (including, without limitation, shares of Common Stock that may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and shares of Common Stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for Common Stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, (3) make any demand for or exercise any right or cause to be confidentially submitted or filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock or any other securities of the Company, or (4) publicly disclose the intention to do any of the foregoing for a period commencing on the date hereof and ending on the 180th day after the date of the Prospectus relating to the Offering (such 180-day period, the "Lock-Up Period").

The foregoing restrictions are expressly agreed to preclude the undersigned from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of Common Stock or any other securities of the Company even if such Common Stock or other securities of the Company would be disposed of by someone other than the undersigned, including, without limitation, any short sale or any purchase, sale or grant of any right (including without limitation any put or call option, forward, swap or any other derivative transaction or instrument) with respect to any Common Stock, or any other security of the Company that includes, relates to, or derives any significant part of its value from Common Stock or other securities of the Company.

The foregoing restrictions, including without limitation the immediately preceding sentence, shall not apply to:

- (a) transactions relating to shares of Common Stock or other securities acquired in the open market after the completion of the Offering or acquired in the Offering from the Underwriters;
- (b) bona fide gifts, sales or other dispositions of shares of any class of the Company's capital stock, in each case, that are made exclusively between and among the undersigned or members of the undersigned's family, or affiliates of the undersigned, including its partners (if a partnership) or members (if a limited liability company); provided that it shall be a condition to any transfer pursuant to this clause (b) that (1) the transferee/donee agrees to be bound by the terms of this Lock-Up Letter Agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee/donee were a party hereto, (2) each party (donor, donee, transferor or transferee) shall not be required by law (including without limitation the disclosure requirements of the Securities Act of 1933, as amended (the "Exchange Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act")) to make, and shall agree to not voluntarily make, any filing or public announcement of the gift, sale or other disposition prior to the expiration of the 180-day period referred to above, and (3) the undersigned notifies B. Riley Securities, Inc. at least two business days prior to the proposed gift, sale or other disposition;
- (c) the exercise of stock options or other equity awards granted pursuant to the Company's stock option/incentive plans, *provided*, that the restrictions shall apply to shares of Common Stock issued upon such exercise or conversion;
- (d) the establishment of any contract, instruction or plan that satisfies all of the requirements of Rule 10b5-1 (a "*Rule 10b5-1 Plan*") under the Exchange Act; *provided*, *however*, that no sales of Common Stock shall be made pursuant to a Rule 10b5-1 Plan prior to the expiration of the Lock-Up Period (as the same may be extended pursuant to the provisions hereof); *provided further*, that the Company is not required to report the establishment of such Rule 10b5-1 Plan in any public report or filing with the Commission under the Exchange Act during the Lock-Up Period and does not otherwise voluntarily effect any such public filing or report regarding such Rule 10b5-1 Plan;
- (e) any transfers by will or intestacy, *provided*, that (1) any transferee agrees to be bound by the terms of this Lock-Up Letter Agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee(s) were a party hereto, (2) no public disclosure or filing under the Exchange Act shall be voluntarily made during the Lock-Up Period and (3) any required filing under the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (e);
- (f) any transfers pursuant to a court order or settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union, *provided*, that (1) no public disclosure or filing under the Exchange Act shall be voluntarily made during the Lock-Up Period and (2) any required filing under the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (f), unless otherwise prohibited by such court order or settlement agreement;

- (g) transfers or dispositions of shares of capital stock of the Company or any securities convertible into, or exercisable or exchangeable for, such capital stock to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned in a transaction not involving a disposition for value, or, if the undersigned is a trust, to a trustor or beneficiary of the trust, or, if the undersigned is a corporation, partnership, limited liability company or other business entity that controls, is controlled by or is under common control with the undersigned or as part of a disposition, transfer or distribution by the undersigned to partners, limited partners, stockholders, members or equityholders of the undersigned, *provided*, in each case, that (1) any transferee agrees to be bound by the terms of this Lock-Up Letter Agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee(s) were a party hereto, (2) no public disclosure or filing under the Exchange Act shall be voluntarily made during the Lock-Up Period and (3) any required filing under the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (g);
- (h) the conversion of preferred shares of the Company, or the conversion, exercise or exchange of any other securities of the Company, into Common Stock or any other securities of the Company, *provided*, that such shares of Common Stock or other securities issued upon conversion, exercise or exchange remain subject to the terms of this Lock-Up Letter Agreement;
- (i) any transfers or commitments to transfer pursuant to a merger, consolidation, tender offer or other similar transaction involving a Change of Control (as defined below) or reverse merger, *provided*, that in the event that such merger, consolidation, tender offer or other such transaction or reverse merger is not completed, such shares of Common Stock or other securities held by the undersigned shall remain subject to the provisions of this Lock-Up Letter Agreement;
- (j) the transfer by the undersigned of shares of Common Stock or any securities convertible into, exercisable or exchangeable for, Common Stock to the Company upon a vesting or settlement event of the Company's securities or upon the exercise of options or warrants to purchase the Company's securities on a "cashless" or "net exercise" basis, in each case pursuant to any equity incentive plan of the Company described in the Prospectus and to the extent permitted by the instruments representing such options or warrants outstanding as of the date of the Prospectus, *provided* that (1) the shares received upon exercise or settlement of the option are subject to the terms of this Lock-Up Letter Agreement, (2) no public disclosure or filing under the Exchange Act shall be voluntarily made during the Lock-Up Period and (3) any required filing under the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (j), including that the securities remain subject to the terms of this Lock-Up Letter Agreement;
- (k) the transfer of shares of Common Stock or securities convertible into, or exercisable or exchangeable for, shares of Common Stock to the Company in connection with the termination of the undersigned's employment with the Company, *provided*, that (1) no public disclosure or filing under the Exchange Act shall be voluntarily made during the Lock-Up Period and (2) any required filing under the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (k); and

(1) transfers that are approved by the prior written consent of B. Riley Securities, Inc.

"Change of Control" shall mean the consummation of any bona fide third party tender offer, merger, consolidation or other similar transaction, in one transaction or a series of related transactions, the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the voting capital stock of the Company (or the surviving entity).

If the undersigned is an officer or director of the Company, (i) B. Riley Securities, Inc. that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, B. Riley Securities, Inc. will notify the Company of the impending release or waiver and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by issuing a press release through a major news service (as referred to in FINRA Rule 5131(d)(2)(B)) or any other method permitted by FINRA Rule 5131 at least two business days before the effective date of the release or waiver. Any release or waiver granted by B. Riley Securities, Inc. hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if both (a) the release or waiver is effected solely to permit a transfer not for consideration, and (b) the transferee has agreed in writing to be bound by the same terms described in this letter that are applicable to the transferor, to the extent and for the duration that such terms remain in effect at the time of the transfer.

In addition, the undersigned agrees that, without the prior written consent of B. Riley Securities, Inc., on behalf of the Underwriters, it will not, during the Lock-Up Period, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock. In furtherance of the foregoing, the Company and its transfer agent are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Lock-Up Letter Agreement.

It is understood that, if the Company notifies the Underwriters that it does not intend to proceed with the Offering through B. Riley Securities, Inc., or if the Underwriters notify the Company that they do not intend to proceed with the Offering, the undersigned will be released from its obligations under this Lock-Up Letter Agreement.

The undersigned understands that the Company and the Underwriters will proceed with the Offering in reliance on this Lock-Up Letter Agreement.

Whether or not the Offering actually occurs depends on a number of factors, including, without limitation, market conditions. Any Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

The undersigned acknowledges and agrees that the Underwriters have not provided any recommendation or investment advice nor have the Underwriters solicited any action from the undersigned with respect to the Offering and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate.

This Lock-Up Letter Agreement and any transaction contemplated by this Lock-Up Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to conflict of laws principles that would result in the application of any other law than the laws of the State of New York (other than Section 5-1401 of the General Obligations Law).

This Lock-Up Letter Agreement shall automatically terminate upon the earlier to occur, if any, of (1) the withdrawal by the Company of the registration statement relating to the Offering, (2) the termination of the Underwriting Agreement before the sale of any Stock to the Underwriters or (3) December 31, 2021, in the event that the Underwriting Agreement has not been executed by that date.

[Signature page follows]

Agreement and that, upon request, the undersigned will execute any additional doc obligations of the undersigned shall be binding upon the heirs and executors (in the cathe undersigned.					
Very tru	ly yours,				
Ву:					
I	Name:				
	Title:				
Dated:					
[Signature Page to Lock-Up Agreement]					
	_				

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Letter

#### **EXHIBIT B**

#### **Form of Press Release**

IN8bio, Inc. [*Insert date*]

IN8bio, Inc., (the "*Company*") announced today that B. Riley Securities, Inc., the sole book-running manager in the Company's recent public sale of [●] shares of common stock and the other underwriters of such offering whose consent is required are [waiving] [releasing] a lock-up restriction with respect to [●] shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on [*insert date*], and the shares may be sold or otherwise disposed of on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in Amendment No. 4 to the Registration Statement on Form S-1 (File No. 333-249530) of IN8bio, Inc. of our report dated March 31, 2021, on our audits of the financial statements of IN8bio, Inc as of December 31, 2020 and 2019 and for the years then ended. We also consent to the reference to our firm under the heading "Experts."

/s/ CohnReznick LLP

Tysons, Virginia July 16, 2021