UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission File Number 001-39692

IN8BIO, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of $10.00 per share of the Registrant's common stock on the Nasdaq Capital Market on July 30, 2021, was $61.5 million. The Registrant has elected to use July 30, 2021, which was the initial trading date of the Registrant's common stock on the Nasdaq Capital Market, because on the last day of the Registrant's most recently completed second fiscal quarter, the Registrant was a private company.

The number of shares of Registrant's Common Stock outstanding as of March 10, 2022 was 18,812,267.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2022 Annual Meeting of Stockholders of the Registrant, or the Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2021.

Table of Contents

In this report, unless otherwise stated or the context otherwise indicates, the terms "IN8bio, Inc.," "the company," "we," "us," "our" and similar references refer to IN8bio, Inc. "IN8BIO," "INEIGHTBIO," the IN8BIO logo, DeltEx and other trademarks, trade names or service marks of IN8bio, Inc. appearing in this Annual Report are the property of IN8bio, Inc. All other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ 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 10, 13, 17, 21 and 24 of this Annual Report were created with biorender.com.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- 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 and other geopolitical tensions, such as Russia's recent incursion into Ukraine, on our business, our industry and the economy;
- 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;
- 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 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.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" and elsewhere in this Annual Report. A summary of selected risks associated with our business are set forth below. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained

in this Annual Report. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

PART I

Item 1. 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 gamma-delta T cells in immune function and activation, against diseases such as cancer, underscores their therapeutic potential across a wide range of solid and hematologic malignancies. We develop *ex vivo*-expanded and activated gamma-delta T cell candidates based upon our deep expertise in gamma-delta T cell biology, proprietary genetic engineering and cell-type specific manufacturing capabilities, which we refer to collectively as our DeltEx platform. Our platform employs allogeneic, autologous and genetically modified approaches to advance 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 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 high-risk leukemias that are undergoing hematopoietic stem cell transplantation, or HSCT. For INB-200, we expect to report initial topline Phase 1 clinical trial results in the second half of 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 plan to initiate a new Phase 1b/2 clinical program INB-400 in which both allogeneic and autologous genetically modified gamma-delta T cells will be assessed in both relapsed and newly diagnosed GBM patients. A portfolio of preclinical programs, including INB-300, focused on addressing various solid tumors using a dedicated gamma-delta chimeric antigen receptor T cell, or CAR-T cell, construct is also in progress. We will continue to advance internal research, including the application of our proprietary DeltEx DRI approach into additional solid tumor indications. We expect to file several investigational new drug applications, or INDs, for our pipeline product candidates through 2023, with the first investigational new drug application, or IND, expected to be filed by the second half of 2022.

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 rapidly and directly kill tumors. Chemotherapy, however, can also result in residual tumor cells that are chemotherapy resistant and lead to disease recurrence.

Recent studies show that the injury response to DNA damage from chemotherapy in live tumor cells can promote anti-tumor immune activity and impact subsequent tumor rejection. These positive immune effects are obstructed 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, 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. 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 also testing the safety of a donor-derived, expanded, activated, non-genetically modified gamma-delta T cell therapeutic candidate, or DeltEx Allo, 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. Our capabilities stem from the knowledge and experience passed to our team by our scientific co-founder, Lawrence Lamb, PhD, who has been working with cellular therapies and specifically gamma-delta T cells since the early 1990s. Dr. Lamb published some of the earliest manufacturing methods for certain subsets of gamma-delta T cells and has extensive experience scaling and conducting GMP manufacturing. He was an inspector and auditor for the Foundation for the Accreditation of Cellular Therapy, or FACT for over 20 years. We believe that our unique corporate insights into the advanced manufacturing and biology of gamma-delta T cells provide us with an innovative approach toward treating cancer that capitalize on the particular properties of gamma-delta T cells. We have advanced two novel programs into the clinic that have the potential to demonstrate durable tumor responses. 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.

Our Pipeline

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

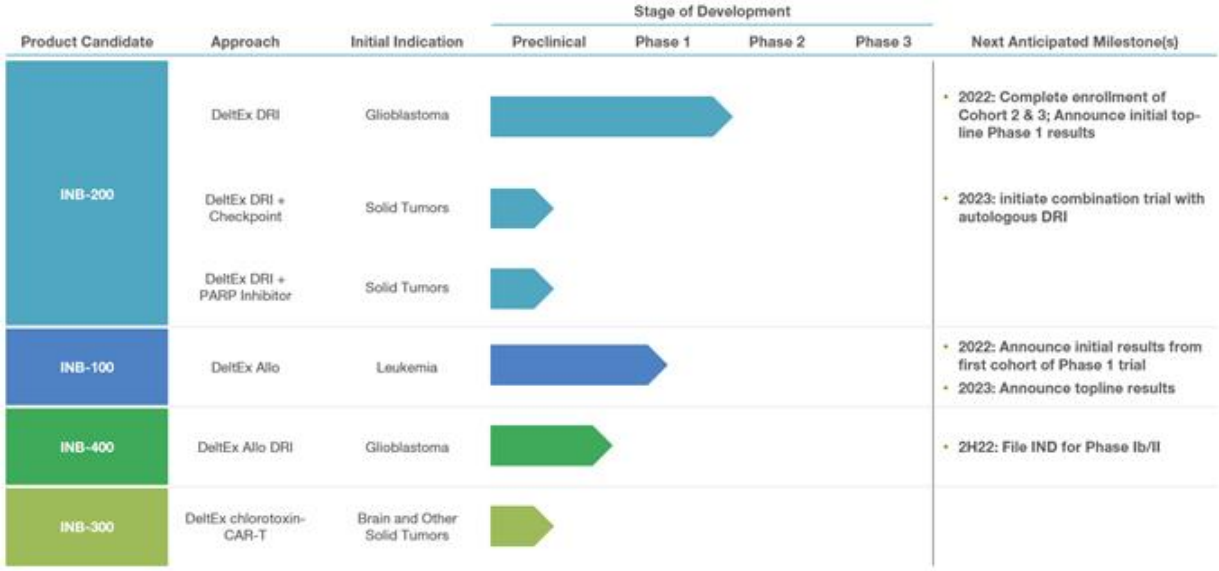

Figure 1. Pipeline Chart

Our lead product candidate, INB-200, is a genetically modified autologous gamma-delta T cell currently in a Phase 1 clinical trial. In preclinical studies, our DeltEx DRI technology has been shown to allow gamma-delta T cells to survive and remain functional at therapeutic and supratherapeutic concentrations of chemotherapy. Such levels, which would normally be toxic to immune cells, allow our DeltEx DRI gamma-delta T cells to be used concomitantly with chemotherapy for the treatment of multiple solid tumor cancers. We engineered INB-200 to be resistant to alkylating agents such as temozolomide, or TMZ, a class of chemotherapeutic drugs used in the treatment of GBM and other cancers. This could allow INB-200 to be administered in combination with the current standard-of-care in the newly diagnosed treatment setting where survival has remained at less than 2.5 years since 2005. In preclinical studies, we demonstrated that such concomitant combinations resulted in durable improvements in long-term overall survival and complete eradication of tumor in 80% of animals. The current INB-200 Phase 1 clinical trial is a dose escalation protocol for newly diagnosed GBM patients at the Heersink School of Medicine and O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham, or UAB. The protocol is designed to evaluate single and multi-dose schedules of a fixed concentration of gene-modified chemotherapy-resistant gamma-delta T cells. We expect to report the initial topline results from this Phase 1 clinical trial in the second half of 2022.

INB-100, our first off-the shelf allogeneic DeltEx product candidate, was developed to demonstrate the safety of donor-derived expanded and activated gamma-delta T cells that do not undergo additional genetic modification. This product candidate is being administered in a dose-escalation Phase 1 clinical trial for the treatment of patients with high-risk leukemias that are undergoing HSCT. 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. This Phase 1 dose-escalation clinical trial of INB-100 in allogeneic HSCT patients is being conducted 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 allogeneic DeltEx DRI product candidate to treat solid tumor cancers, including newly diagnosed GBM, which will also further confirm the clinical efficacy of autologous DeltEx therapy. We plan to utilize clinical data from the Phase 1 clinical trials of INB-200 and INB-100 to provide the safety data necessary to support submission of an IND for INB-400 by the second half of 2022 for the treatment of newly diagnosed and relapsed GBM patients. INB-400 will evaluate the safety of genetically modified allogeneic DeltEx DRI gamma-delta T cells and assess their clinical activity in relapsed GBM patients while also confirming the safety and efficacy of autologous DeltEx DRI gamma-delta T cells in a newly diagnosed GBM patient population. Eventually we expect this construct will be assessed in a broader range of solid tumor cancer populations.

We are also developing a broad portfolio of preclinical programs in our efforts to effectively target and eliminate cancer. INB-300 is a preclinical program focused on developing CAR-T enabled DeltEx DRI product candidates for which we expect to target both brain tumors and additional extracranial solid tumors. Additional programs are focused advanced manufacturing methodologies and on logical combinations with other therapies approved by the U.S. Food and Drug Administration, or FDA. Such combinations can drive synergies and enhance the antitumor activity of compounds such as checkpoint inhibitors, and DNA damage response (DDR) inhibitors such as poly (ADP-ribose) polymerase, or PARP, inhibitors, or PARPi. At the 2021 meeting of the Society for Immunotherapy of Cancer, or SITC, we showed that the use of alkylating chemotherapies in combination with PARPi could act synergistically to reduce tumor size and significantly increase expression of NKG2D ligands. A combination of Temozolomide (TMZ) with PARPi (niraparib) increased expression of stress ligands on multiple solid tumor cell lines in vitro with up to a 29 times increase in mRNA expression of NKG2D ligands. Increases were seen in human classical and proneural human glioblastoma xenolines as well as in SB28 cells, a treatment-resistant mouse glioma cell line to closely resembles predicted treatment responses of advanced human GBM tumors. Increased expression of NKG2DL results in a more visible target for gamma-delta T cells, enhancing both recognition and killing. We believe these data demonstrating the ability to upregulate the expression of innate immune markers such as NKG2DL on tumor cells are important because it significantly increases tumor antigen density and immune activation through increased avidity. Data presented at the 2021 American Society of Hematology, or ASH, annual meeting demonstrated that antigen density on the surface of tumor cells is a critical modulator of CAR-T function. Higher antigen density involving thousands of antigen-ligand interactions is required for full CAR-T cell activation, whereas lower antigen levels were found to be associated with resistance to CAR therapy and/or a higher incidence of relapse.

As of December 31, 2021, our intellectual property portfolio 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. Our future product candidates could incorporate additional proprietary genetic alterations designed to make them resistant to other chemotherapies utilized to treat multiple types of solid tumor cancers. Our patents 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.

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 glioblastoma, or GBM. We are conducting a Phase 1 dose-escalation clinical trial assessing single and multiple dosing schemas at UAB. We expect to report topline results from this Phase 1 trial in the second half of 2022. 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 company-sponsored INDs***. Based on updated FDA guidance, we plan to submit an initial autologous investigational new drug application, or IND, for INB-400, in the second half of 2022 with a supplemental IND covering the allogeneic cells shortly thereafter. We intend to leverage the clinical data from our Phase 1 clinical trials of INB-200 and INB-100 to provide the safety data necessary to support the IND submission in newly diagnosed and relapsed GBM patients. 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 several INDs using technology assessed in INB-200, including in combination with other therapeutics and in other solid tumors outside of GBM, 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 along with advanced manufacturing methods 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. 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.

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 prior 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.

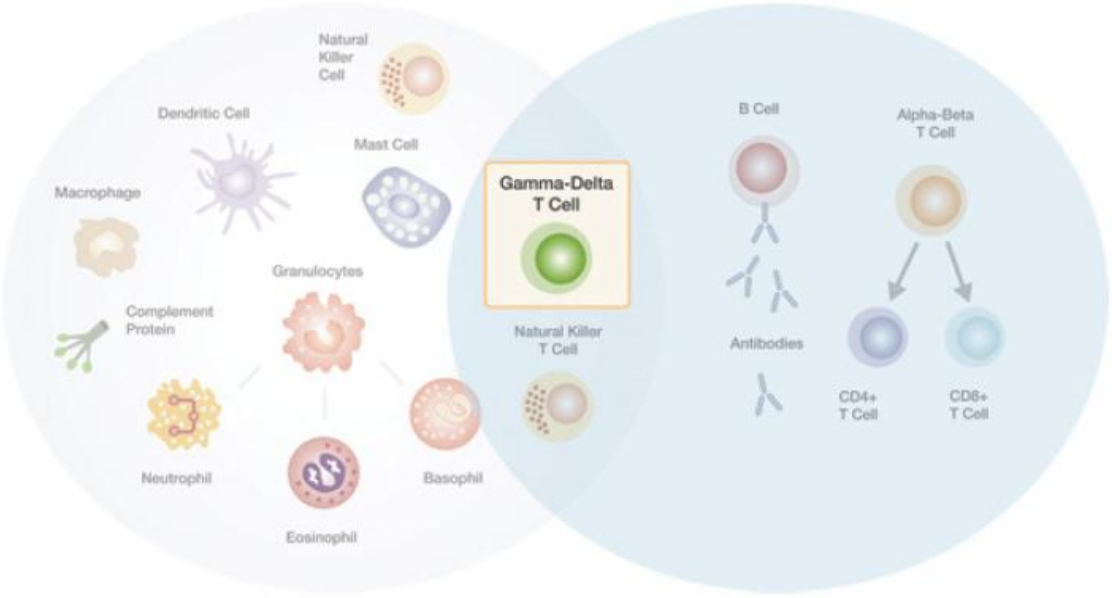

Figure 2. Gamma-Delta T Cells: Innate and Adaptive Immune System Characteristics

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. Taken together, the unique properties of gamma-delta T cells indicate that their therapeutic application can overcome many of these challenges. Simplistically, gamma-delta T cells are a combination of both worlds, with the memory and persistence features of the adaptive immune cells along with the recognition, killing and safety features of the innate immune cells.

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, the FDA has approved six autologous CAR-T cell therapies, KYMIRAH®, Yescarta®, Breyanzi®, Abecma® TECARTUS®, and CARVYKTI®, which have been transformative in the treatment of certain hematological cancers, 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, one of the major drivers of cytokine release syndrome, or CRS, which can lead to substantial morbidity and mortality with immune CAR-T therapies; 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 has 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. More recently, following early CAR-NK cell clinical data, there have been increased questions about the persistence of NK cell based cellular therapies and the durability of response.

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. As gamma-delta T cells bridge between the innate and adaptive immune response, they are thought to have greater persistence than NK cells. Our own histopathological data from the INB-200 clinical trial has demonstrated both an increase in the number gamma-delta T cells and their continued presence in the TME ~150 days following infusion of our DeltEx DRI modified gamma-delta T cells. The University of Pennsylvania published data in the journal *Nature* in February 2022 that, demonstrated decade-long leukemia remissions in two patients with chronic lymphocytic leukemia. The data showed persistence of highly activated CD4+ CAR-T cells including a large population of gamma-delta CAR-T cells that prominently expanded in one patient along with CD8+ CAR T cells.

Gamma-delta 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 alpha-beta 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, gamma-delta T cells can kill in situations where other immune cells cannot, such as alpha-beta T cells through the downregulation of MHC expression NK cells through inhibition by 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.

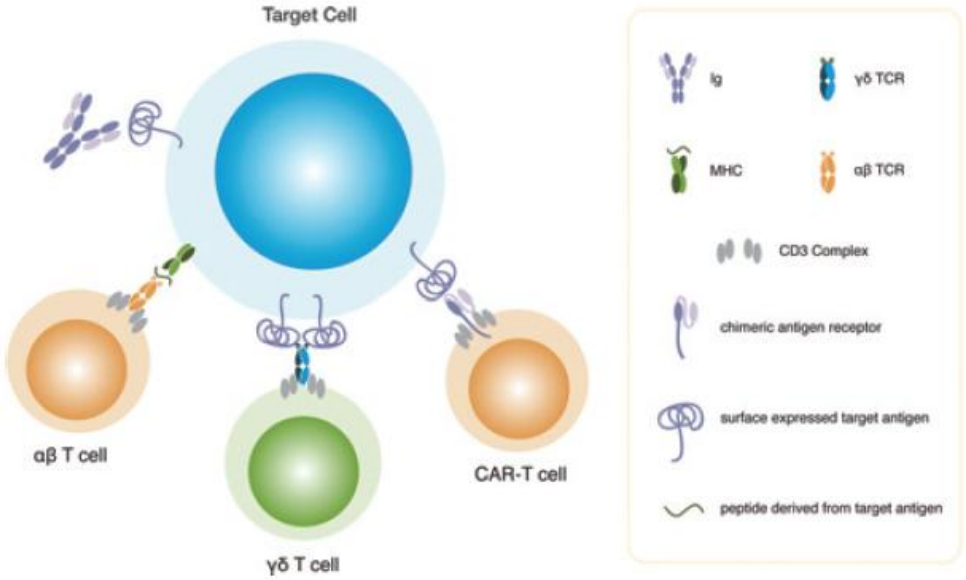

Figure 3. "Nature's CAR-T Cell"

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 as shown in Figure 4.

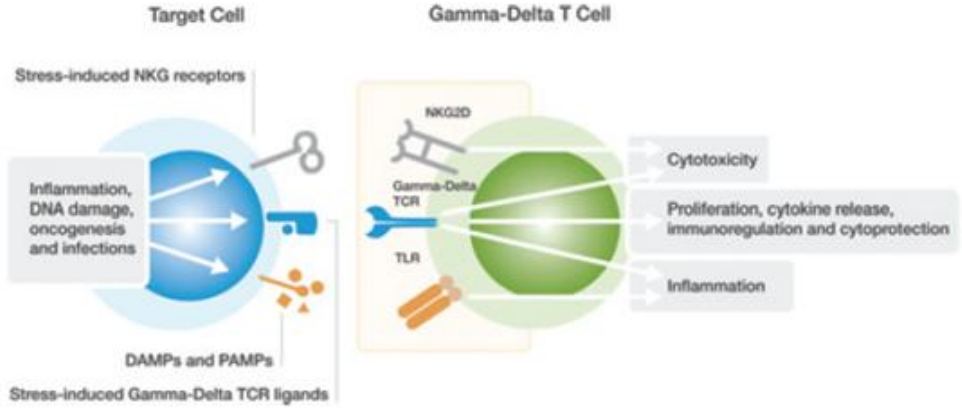

Figure 4. Innate Immune Cell Receptors of Gamma-Delta T Cells

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.

- ***Broad tumor recognition overcomes surface antigen heterogeneity***. 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.

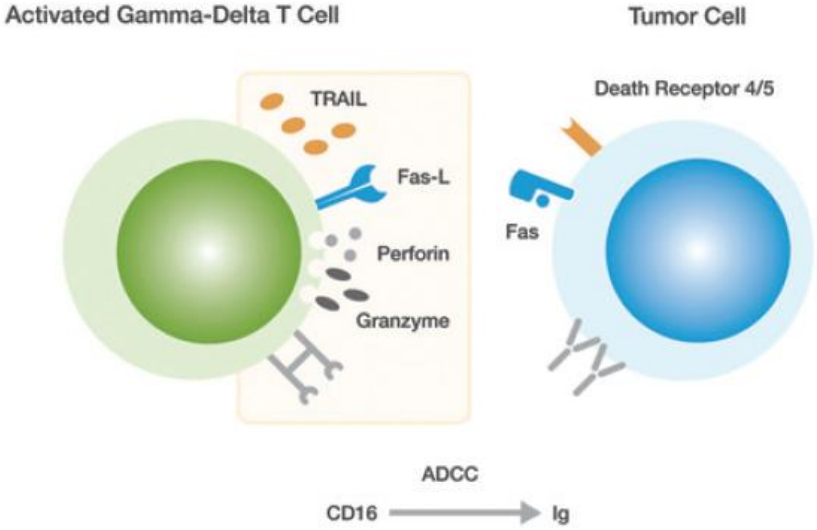

Figure 5. Multiple Cell-Killing Mechanisms of Activated Gamma-Delta T Cells

Opportunities for Gamma-Delta T Cells in Cancer

The therapeutic potential of gamma-delta T cells is supported by observations over almost 30 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.

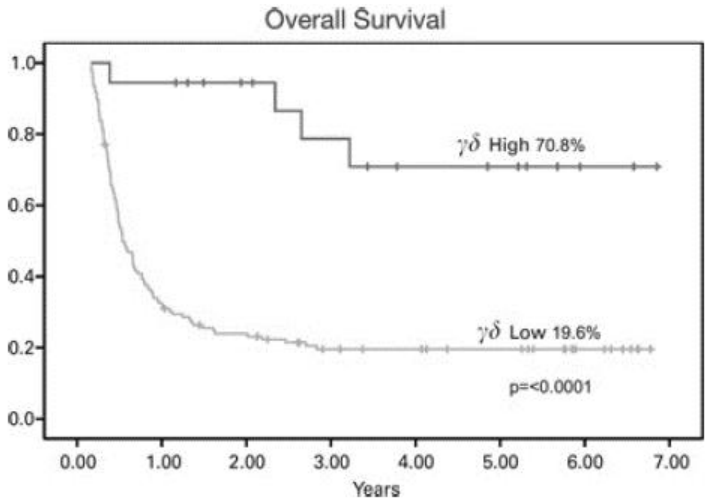

Figure 6. Correlation of Naturally Occurring Gamma-Delta T cells and Long-Term Survival in Leukemia

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 gamma-delta 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.

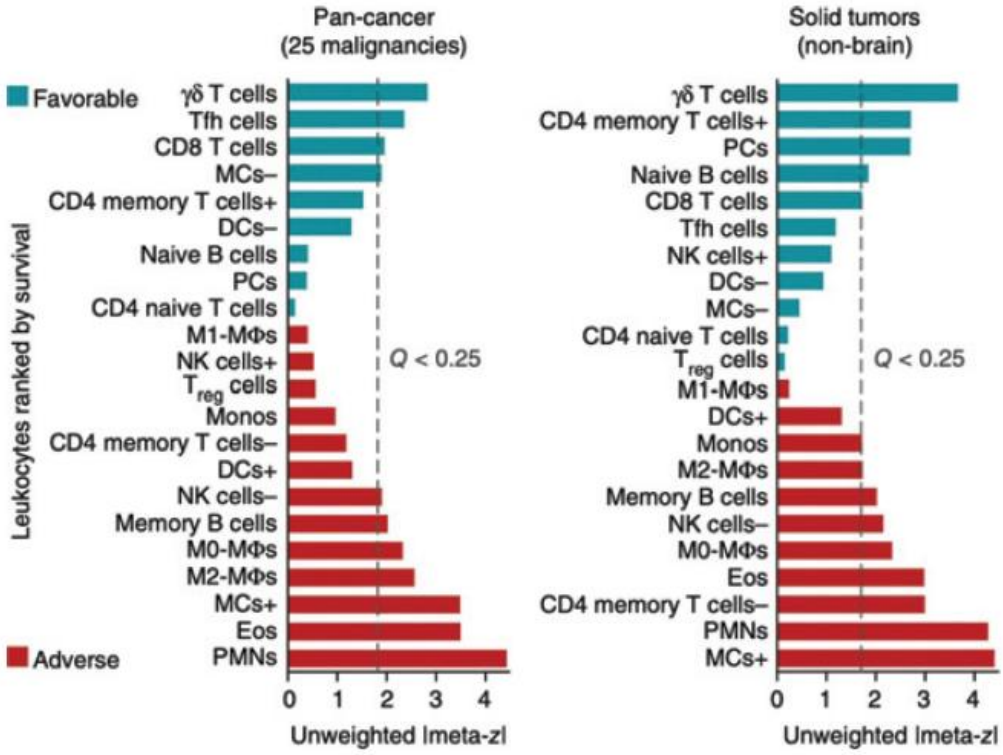

Figure 7. Prognostic Association of Tumor Infiltrating Lymphocytes and Survival Outcomes

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 “de-bulk” the tumor. This opens 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 Approach

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 only 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 Vd2+ Versus Vd1+ Gamma-Delta T Cells as Therapy for Solid Tumors

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 (APC), which can process and present antigens, recruit and activate additional immune cell types, a function that has not been documented for the Vd1+ T cell compartment and may make the Vg9Vd2 subset more attractive for use in solid tumor cancers. 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 may have certain advantages over the Vd1+ subset in certain indications. While Vd1+ cells have shown greater persistence in the autologous setting, this increased persistence in the allogeneic setting (other than allogeneic HSCT) is essentially irrelevant as host immune system recovery would result in their rejection by host NK cells. Additionally, Th1 effector Vd1+ cells can be reprogrammed to a tumor promoting Th17, or IL-17 secreting, subtype after entering the microenvironment of certain tumors. 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 within the TME remains a possibility. In contrast, Vd2+ cells are not known to produce Th17 or pro-tumoral subtypes.

We are a gamma-delta T cell company and are agnostic to Vd2+ versus Vd1+ subtypes. We believe each has a role and indications in which they may make sense based on the tumor biology and desired cellular mechanism of action. Our CSO, Dr. Lamb was in fact the first to publish a protocol for the expansion and manufacturing of Vd1+ gamma-delta T cells in 1997. We are currently advancing programs utilizing both Vd2+ and Vd1+ cells, using our cell-type specific expansion protocols. We have developed our DeltEx platform to enable us to expand, activate and genetically modify gamma-delta T cells at scale, producing cells which are viable, functional and can be cryopreserved while maintaining their cytotoxicity.

Our 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 adjunct 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, published in the Nature portfolio journal *Scientific Reports* in October 2021, 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 clinical trial assessing multi-dose schedules in patients with newly diagnosed GBM, which has been initiated by L. Burt Nabors, M.D. at UAB. We expect to report the topline Phase 1 clinical trial results in the second half of 2022.

GBM Overview

GBM is a particularly aggressive form of brain cancer, in which tumor cells invade the surrounding neural tissue, rendering a cure with surgical resection and chemotherapy unlikely. 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)) while median overall survival for GBM patients remains about 16 months irrespective of tumor methylation status. Ultimately, virtually all patients will relapse, creating a significant unmet medical need with a potential global market opportunity greater than $4 billion.

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 15-16 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 that may be 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 and continue seeding tumor persistence.

Our gamma-delta T cell technology has the potential to be a more durable therapy due to limited resistance mechanisms developing in response to it. 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. CAR-T therapies or any targeted therapy that targets a single antigen is prone to loss of efficacy over time as tumor cells lose, downregulate or shed the tumor target in response to persistent stimulation. Unlike other CAR-T therapies that are reliant on a single tumor target to ensure tumor cell engagement, our technology generates a stressor that upregulates ligands, i.e. NKG2D ligands, that then activate the gamma-delta T cells. These ligands comprise an intrinsic stress mechanism that is upregulated with hypoxia, DNA instability or any condition that generates circumstances that may limit cell viability. Therefore, there is less likelihood of loss of NKG2D ligands as it is impossible to eliminate all stressors that lead to upregulation of NKG2D ligands that activate gamma-delta T cells. Our unique approach seeks to increase tumor antigen density on the surface of tumor cells to drive activation of immune responses and via an antigen that is tumor agnostic. By pairing our therapy with TMZ we are harnessing the ability of TMZ to upregulate multiple NKG2D ligands to ensure the gamma-delta T cells have the appropriate activation signals already in place to maximize their activity.

Nevertheless, we intend to investigate TMZ and other chemotherapy combinations in the future that may drive this NKG2D expression further. This may be able to drive to deeper antitumor immune responses that could lead to prolonged progression free survival and increased overall survival and would be combinations to assess in future combination studies.

We believe newly diagnosed GBM may be the ideal indication to assess the potential of INB-200 to drive clinical antitumor activity due to the intrinsic role that TMZ plays in its therapy and with the ability to ensure targeted therapeutic delivery of the tumor site. A recent third-party paper analyzing the impact of pre-conditioning on the TME to enhance solid tumor CAR-T cell therapy indicated that single-antigen targeting CAR-Ts have been hampered by tumor antigen escape, immune suppression, and lack of T cell trafficking. The inability to infiltrate the tumor site was due largely to the trapping of adoptively transferred cells in first-pass tissues, such as the lung and liver rather than trafficking to the targeted tumor sites. We believe our approach minimizes the risk of tumor antigen escape because TMZ causes the upregulation of cellular stress signals, consisting of multiple polyclonal ligands that can be recognized by the gamma-delta T cell. Furthermore, our DeltEx DRI approach in newly diagnosed GBM was specifically designed to overcome challenges of T cell localization. The administration of DeltEx DRI cells in INB-200, through an intracranial catheter, directly to the tumor resection site ensures access of the cells to the tumor site and may increase the effector to target, or E:T ratio, and permits localizing the therapy to the specific target area, improving 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. Newly diagnosed GBM patients have a more intact immune system that does not have the immune suppression resulting from multiple rounds of earlier chemotherapy and/or radiation as do relapsed populations in whom the CAR-T therapies have been assessed. All immune therapies require an adequate baseline immune activity to maximize their effect. Hence, introducing this therapy in a newly diagnosed population may ensure that the patients have more robust immune systems available to fully mobilize upon tumor cell destruction caused by gamma-delta cell therapy.

INB-200 — Phase 1 Clinical Trial

We are conducting an investigator-initiated Phase 1 repeat dose escalation trial of INB-200 at UAB. We expect this trial to enroll up to 19 patients evaluable for dose-limiting toxicity with newly diagnosed GBM who have completed standard induction therapy with TMZ chemotherapy and radiotherapy and are eligible to initiate maintenance therapy with TMZ.

The primary endpoint of this trial is to assess the safety and tolerability of expanded and activated autologous MGMT genetically modified gamma-delta T cell infusion. Safety will be assessed with single and multiple infusions of $1x10^7$ DeltEx DRI gamma-delta T cells administered through a fenestrated intracranial catheter. Secondary endpoints include overall survival, time to progression and response. We also assess biologic activity, including serum and cellular cytokines, immune cell composition, biomarkers and cell-free DNA both peripherally and from the cerebral spinal fluid, if available. This clinical strategy takes advantage of maximizing gamma-delta T cell cytotoxicity by administering it along with TMZ chemotherapy. The tumor is experiencing maximum stress, increased immunogenicity and expressing high levels of NKG2D ligands required to stimulate the gamma-delta T cells as a result of treatment with TMZ. Further, the natural lymphodepletion achieved by standard

of care TMZ ensures that the chemo-resistant gamma-delta cells remain enriched in the vicinity of tumor to eliminate or slow growth of residual tumor.

Eligible patients 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 from the immunosuppressive environment created by resident tumor. 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 induction therapy consisting of 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.

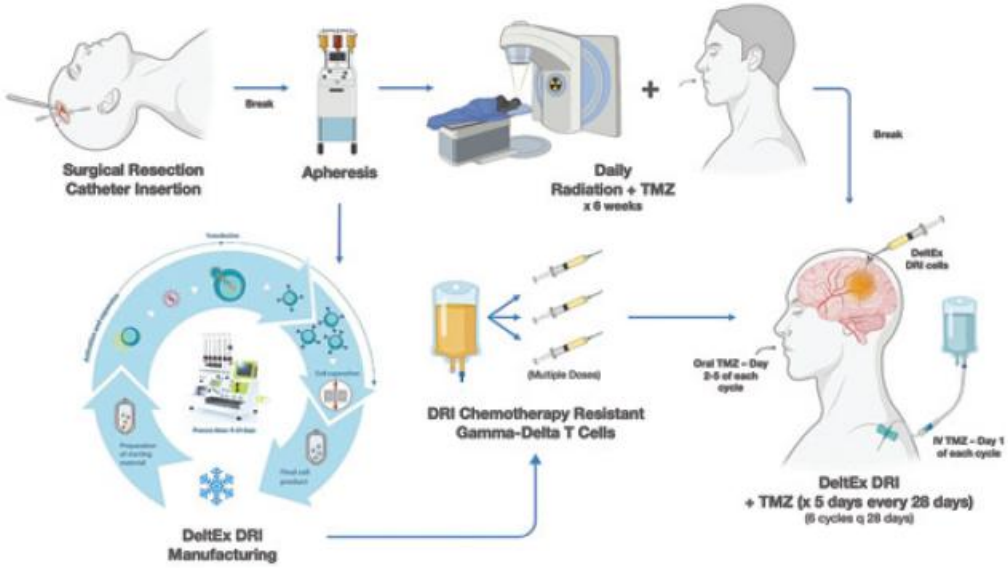

Figure 9. INB-200 Administration Protocol

The decision to combine INB-200 in the newly diagnosed GBM setting as an adjunct 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 with immune cells that are as healthy as possible. By combining INB-200 with maintenance TMZ, we hope to deepen responses achieved by induction chemoradiation by further eliminating residual tumor and driving prolonged immune responses. In addition, introducing gamma-delta T cells in a newly diagnosed population of patients ensures that these patients' immune systems are as robust and active as feasible to take advantage of tumor elimination created by the gamma-delta T cells. Patients are dosed with adjunct 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.

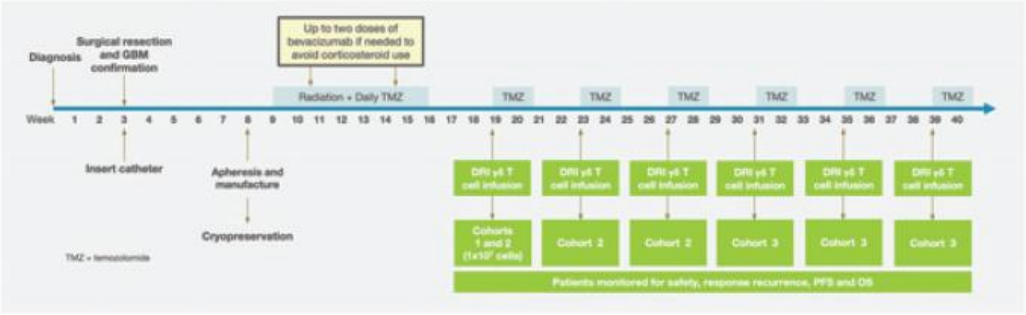

Figure 10. Treatment and Manufacturing Timeline of the INB-200 Phase 1 Trial

Twelve patients with newly diagnosed GBM have been enrolled in this trial and a total of six patients have received treatment as of December 31, 2021. The patients in cohort 1 each received a single dose of INB-200, following a minimum of 30 days for safety observation. Three patients comprising the first dose cohort have received a single dose of INB-200 and one patient remains alive at 17 months post-treatment, having exceeded their expected progression free survival and overall survival as of December 31, 2021. 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. The second cohort, in which patients will receive three doses of INB-200 28 days apart has begun enrollment with one patient in this cohort having completed all three doses as of December 31, 2021, with no treatment-related dose limiting toxicities observed. Additional patients are enrolled in cohort 2 and we are actively recruiting additional patients into this trial. A third cohort will initiate enrollment in 2022 where patients will receive up to six doses of INB-200, 28 days apart. Following treatment, all patients will be monitored for biologic correlates, time to disease progression and for overall survival. We expect to report topline results from this Phase 1 clinical trial by the second half of 2022, which data we expect to present at medical conferences in 2022.

Six patients in the first multidose cohort (cohort 2) have been enrolled, with two of the patients dosed as of December 31, 2021. As previously disclosed, the earliest patient 007 was a 74 year-old male with MGMT unmethylated and IDH-wild-type GBM who died 22 days after his second dose due to an acute cardio-pulmonary event. The investigator and Company's analysis of the patient's prior medical history and the events preceding death were presented to the independent data safety monitoring board and the FDA who all agreed that the death event was unlikely to be related to treatment with INB-200. Protocol modifications to mitigate the risk of severe cardiovascular adverse events was submitted to the FDA to mitigate future similar events. These were deemed reasonable and acceptable, and the study was allowed to continue uninterrupted. We 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 in the single or multidose cohort. 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.

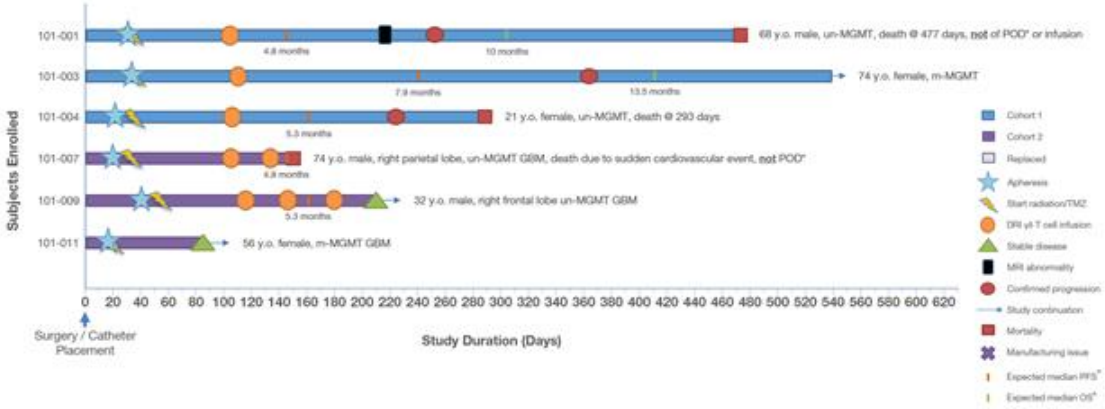

Figure 11. Summary of Patients Enrolled in INB-200 Phase 1 Trial

Figure 11 above depicts treatment outcomes for patients treated as of December 31, 2021. Early data demonstrates that patients have exceeded expected progression free survival based on their age and tumor MGMT status and have exceeded the median progression free survival predicted of this patient population. Patients 001, 003 and 004 had progressive disease, which all occurred beyond their expected median time to progression based on age and MGMT status. Patient 009 is a 32 year-old male with MGMT unmethylated and IDH mutant GBM who has received all three doses in cohort 2. No infusion reactions, cytokine release syndrome, neurotoxicity, or other dose limiting toxicities or serious treatment-emergent adverse events were observed following the three doses. This patient remains clinically asymptomatic and continues to be monitored for progression and overall survival.

Additional patients are enrolled in cohort 2 and we are actively recruiting additional patients into this trial. Delays due to the patient death described above, COVID-19, along with manufacturing failure and withdrawal of patient consent have impacted timing and a number of the patients initially enrolled in cohort 2. We expect to report top-line efficacy and safety results from this Phase 1 clinical trial in the second half of 2022.

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 12 below.

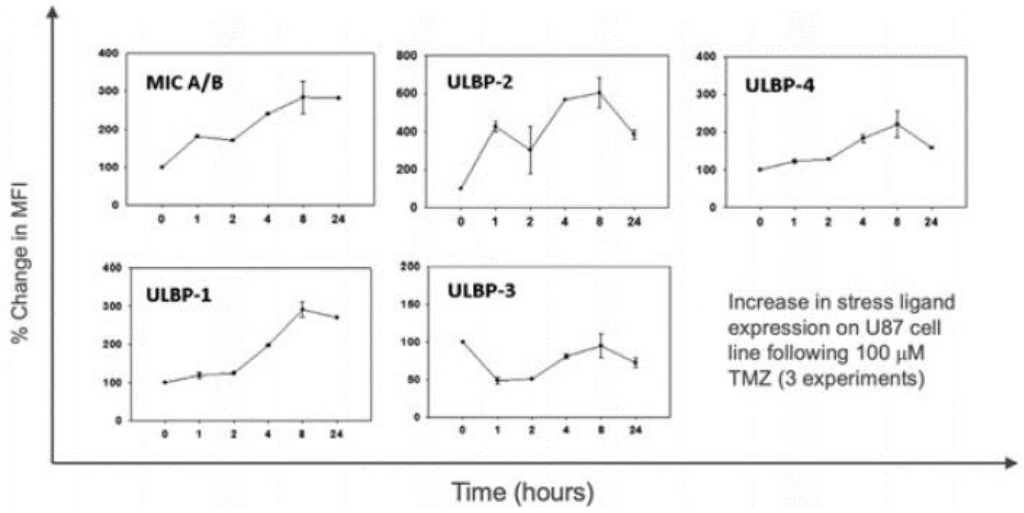

Figure 12. Increased NKG2D Ligand Expression Observed on TMZ-Resistant Tumor Cells Treated with TMZ

As shown in Figure 13 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 14 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% (SD±29%)	76% (SD±31%)	76% (SD±30%)	12% (SD±16%)	48% (SD±33%)
Oct-4	22% (SD±27%)	9% (SD±14%)	89% (SD±34%)	21% (SD±30%)	21% (SD±22%)
Sox-2	35% (SD±30%)	25% (SD±23%)	88% (SD±21%)	14% (SD±19%)	43% (SD±35%)
Nanog	33% (SD±21%)	27% (SD±27%)	71% (SD±30%)	15% (SD±21%)	38% (SD±28%)
Musashi-1	47% (SD±45%)	20% (SD±35%)	57% (SD±27%)	0%	100%

Figure 13. Cancer Stem-Like Cells Co-Express Stem-Cell Markers and NKG2D Ligands

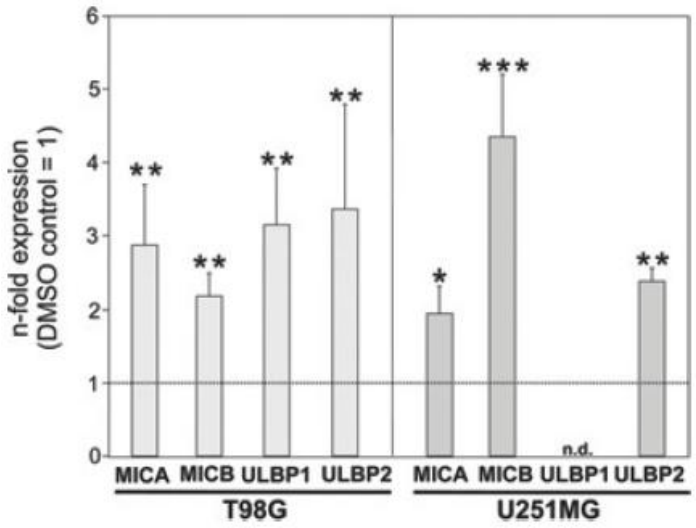

Figure 14. Increased NKG2D Ligand Expression in Glioma Stem Cells Treated with TMZ

There are two principal challenges to clinical application of TMZ treatment in conjunction with gamma-delta 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 15 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.

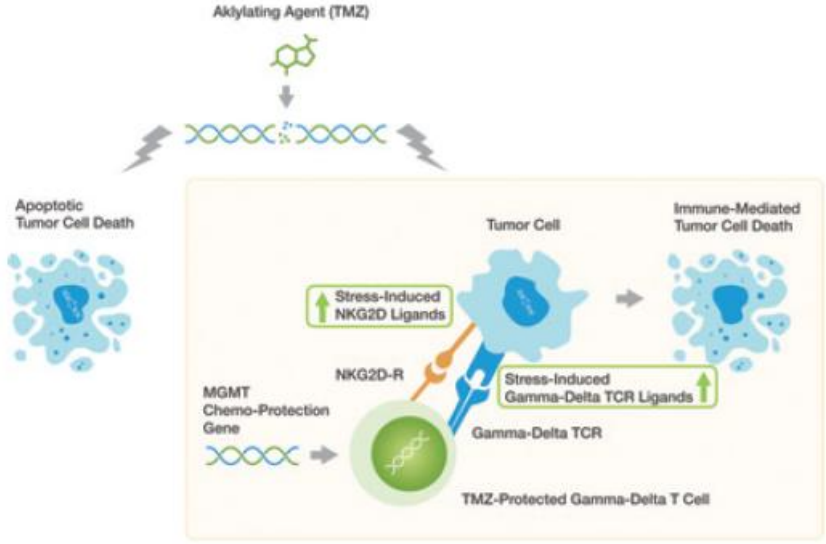

Figure 15. DeltEx DRI Mechanism of Action Targeting the DNA Damage Response (DDR)

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 16 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 μM, of TMZ inhibited the proliferation of unaltered gamma-delta T cells by 50%, whereas a concentration of 383 μM 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.

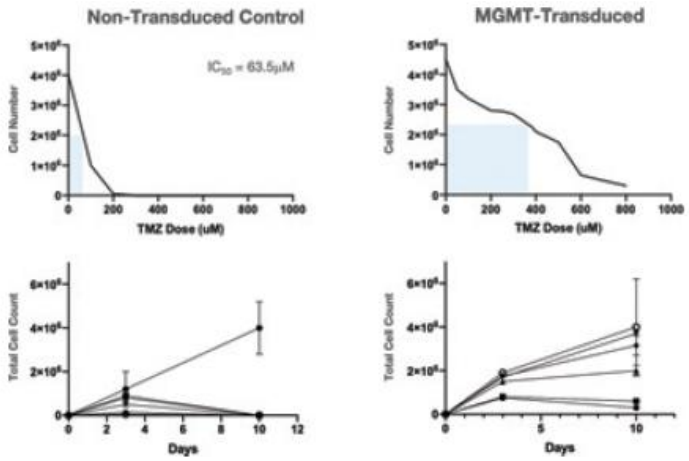

Figure 16. MGMT-Modified Gamma-Delta T Cells Demonstrate Protection Against Killing Effects of TMZ

Our preclinical studies supporting the clinical development of DRI and the submission of an IND to the FDA was peer-reviewed and published online in the Nature portfolio journal *Scientific Reports* in October 2021. 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 18 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 syngeneic 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 17 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.

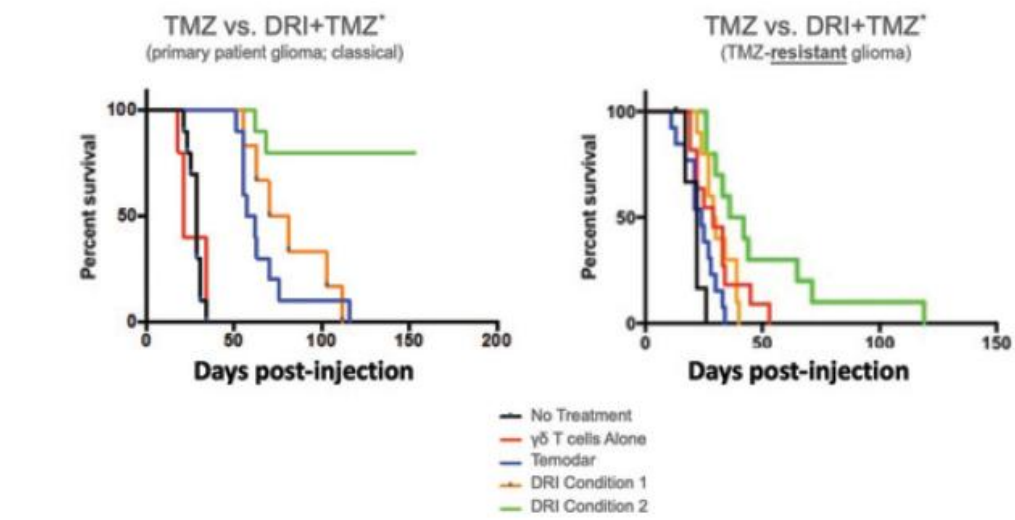

Figure 17. Improved Survival Observed in Both TMZ-Sensitive and TMZ-Resistant GBM Models

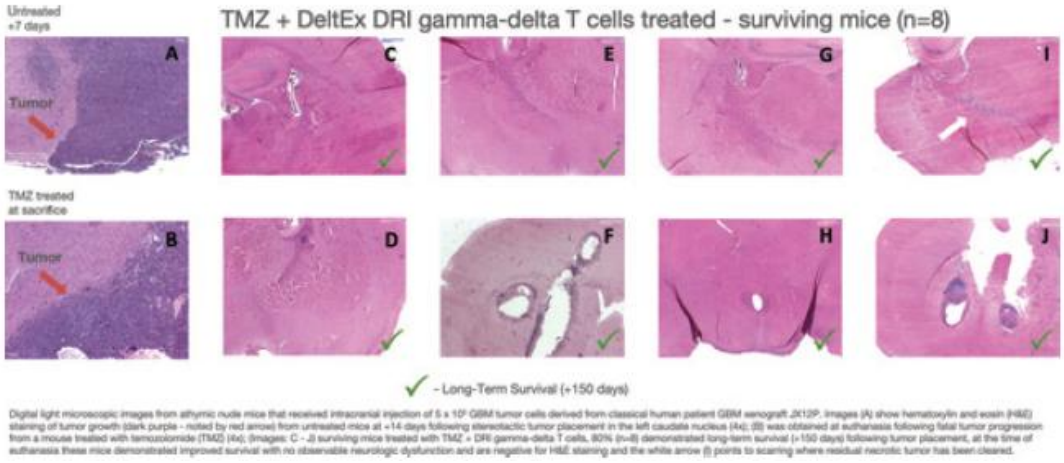

Figure 18. Histopathology Demonstrates No Residual GBM in Mice

These preclinical results are supported by observations of gamma-delta T cells in human cancer patients. As shown in Figure 19 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.

						% γδ T in CD3+*			Ex vivo expanded γδ T					
Patient	Age (years)/ sex	Primary cancer	Metastasis	Previous therapy	Previous Zol. treatment	Before expansion	After ex vivo expansion	Expansion fold	Treat-ments	Max. dose/ treatment (× 10^9cells)	Total dose (× 10^9cells)	Toxi-city[a]	Clinical response	Comment
Group A (GDT dose escalation/Zol. treatment)														
A1	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	—[b]
A3	66/F	Melanoma	Lung, liver	I	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 (GDT non-dose escalation/Zol. treatment)														
B1	67/M	Melanoma	Adrenal grand, heart	I	No	0.3 (0.1)	15.3 (2.2)	728 (111)	6	0.3	1.0	No	SD	
B2	48/F	Adeno-carcinoma	Bone	R	No	2.1 (0.5)	53.6 (9.9)	144 (72)	8	0.5	1.1	Yes	PD	
B3	47/M	Cholangio-carcinoma	Local advanced disease	C	No	1.8 (0.1)	59.5 (4.8)	17 (2)	8	0.4	1.4	No	PD	
B4	65/F	Melanoma	Lung, abdominal mass	I	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	C, R, I	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, abdomen	C	No	9.1 (0.4)	71.7 (3.9)	78 (13)	8	2.2	7.2	Yes	PD	
Group C (GDT/Zol. treatment with other therapy)														
C1	39/F	Breast cancer	Brain (1 met), lung	C	Yes	1.3 (0.1)	22.4 (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]

Abbreviations: C = chemotherapy; CR = complete remission; γδ T = Vγ9Vδ2 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; Zol = Zoledronate; *Represents the mean (s.e.) from 6–8 vaccines. [a]Fever after infusion, A1 also had vomiting. [b]Large bulk of disease but stable. [c]No new lesions. [d]With chemotherapy. [e]With hormonal therapy.

Figure 19. 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 are evaluating its antitumor activity in other tumors commonly treated with TMZ or other alkylating agents such as dacarbazine 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 immuno-oncology drugs, such as checkpoint inhibitors, which may enhance the immunostimulatory activity of these cells. We also plan to assess other mechanisms of chemotherapy resistance and the potential of combinations of drug-resistant gamma-delta T cells with inhibitors of DNA damage repair proteins, such as PARPi that have been shown to increase the expression of stress signals such as NKG2D ligand expression in tumor cells as described above. 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 product consists of allogeneic, expanded activated gamma-delta T cells. We are developing INB-100 for the treatment of patients with hematological malignancies that are undergoing haploidentical, matched-related 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 clinical 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 evaluable for dose-limiting toxicity in the dose escalation portion of this trial. As of December 31, 2021, we have treated three patients in this trial with all three patients remaining in morphologic complete remission, including two patients for periods greater than 1.5 years.

Hematological Malignancies Overview

Hematological malignancies are characterized by an abnormal and excessive proliferation of malignant hematopoietic cells in the marrow. In some patients, these cancerous cells proliferate rapidly, requiring urgent treatment. These include AML, ALL, chronic myeloid leukemia in blast phase and myelodysplastic syndromes, or MDS. There are few curative 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 to repopulate their hematopoietic system.

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 20 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 transfused donor-derived alpha-beta T cells 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 infection and may ultimately fail to prevent leukemic relapse. A match of 8/8 HLA alleles is considered fully matched and is associated with the lowest frequency of GvHD.

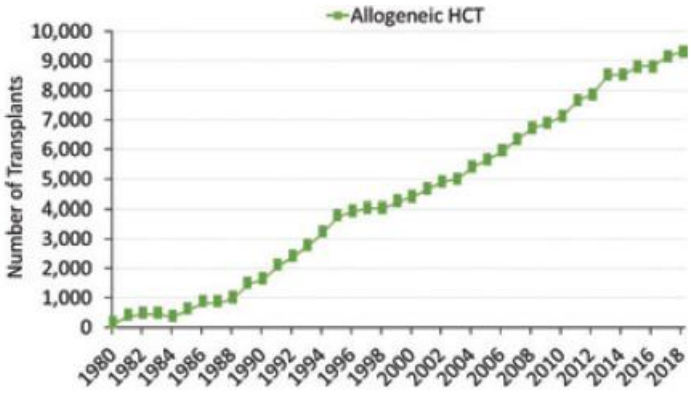

Figure 20. Annual allogeneic HSCT procedures in the United States

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 gamma-delta 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 patients with elevated gamma-delta T cells 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 a functionally closed manufacturing process that is designed to routinely and cost effectively generate the quantities of the cells required for the treatment of patients. Initially we utilized the manufacturing facility at the University of Kansas Cancer Center, the site of our Phase 1 dose-escalation trial with INB-100. Recently, we have shifted our manufacturing to the GMP facility at UAB, in which we have contracted access for several years, to streamline the process

and centralize manufacturing. We have implemented manufacturing process improvements which were included in recent IND modifications that we believe could substantially increase the yield and the number of gamma-delta T cells.

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 2023, clinical data will determine if further expansion to enroll up to 18 patients is warranted in patients with hematologic malignancies.

INB-100 is prepared from donor peripheral blood cells, while in parallel, patients undergo HSCT using donor bone marrow. As depicted in Figure 21 below, INB-100 cells are administered post-engraftment with the goal of providing immunity during the period of immune cell reconstitution.

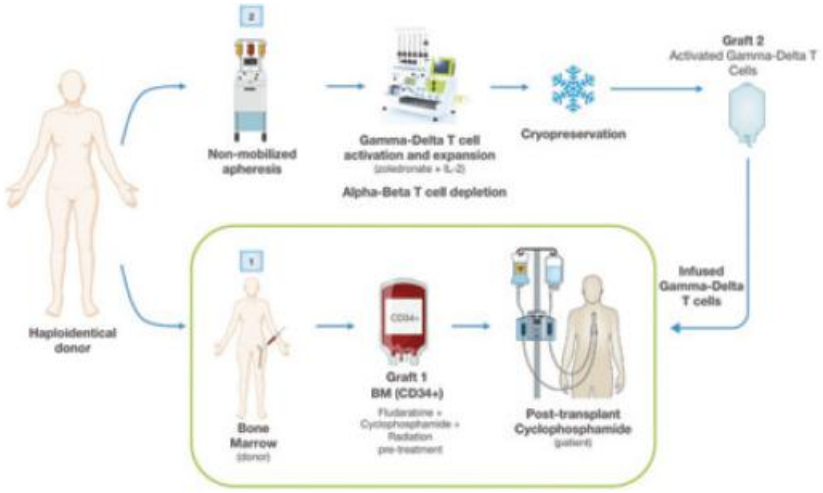

Figure 21. INB-100 Administration

As depicted in Figure 22 below, patients are initially treated using a standard HSCT protocol, originally developed at Johns Hopkins University, or the Hopkins protocol, under which these patients undergo non-myeloablative reduced intensity conditioning regimen using chemotherapeutic agents that destroy their tumor cells as well as their healthy immune cells and post-transplant cyclophosphamide to reduce GvHD. They then undergo allogeneic bone marrow transplant. Prior to the bone marrow transplant, donors undergo leukapheresis to provide the starting material for INB-100 at least seven days prior to 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 and delaying relapse

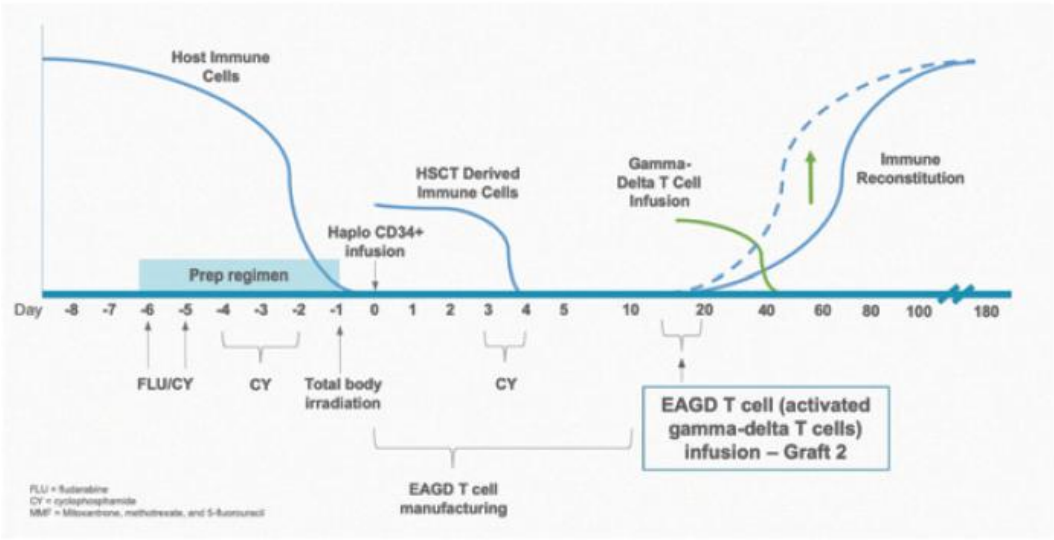

Figure 22. The Projected Composition of Immune Cells in the INB-100 Phase 1 Trial

As represented in Figure 23 below, as of December 31, 2021, six patients have been enrolled in this trial to date with, three infused with INB-100, our DeltEx Allo therapeutic candidate. Three subjects were dosed with INB-100 and one subject (Patient 001) died prior to receiving INB-100 due to cardiogenic shock most likely from post-HSCT cyclophosphamide while two others were unable to be treated due to an inability to generate adequate product. The three patients with relapsed AML treated to date demonstrate that allogeneic gamma-delta T cell therapy has a manageable toxicity profile with the potential for durable responses in high-risk patients. All three subjects who received INB-100 achieved morphologic complete remission and remain in remission with the first two patients at 20.6 months and 18.2 months post treatment, respectively, and the most recent at 6.5 months.

INB-100 continues to demonstrate a manageable safety profile to-date, with no dose-limiting toxicities, no treatment-related grade 3 or greater adverse events, and no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome. Two patients have sustained steroid responsive grade 1-2 skin GvHD while one patient reported grade 2 gastrointestinal GvHD that resolved. No events of grade 3 or greater GvHD has been observed.

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.

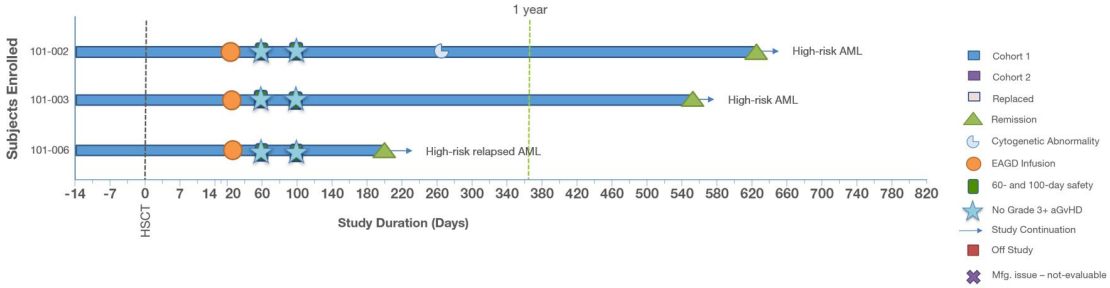

Figure 23. Summary of Patients Treated in INB-100 Phase 1 Trial

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% (± 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 or 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 17 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 being designed to assess the relative risk-benefit ratio of allogeneic versus autologously derived genetically modified gamma-delta T cells for treatment patients with GBM, including patients with newly diagnosed GBM and will also assess the activity of allogeneic cells in the relapsed setting. INB-400 will have 3 cohorts. One cohort will further develop the safety and efficacy profile of autologously delivered modified gamma-delta T cells administered to patients with newly diagnosed GBM. In addition, we will generate initial safety data on the DeltEx DRI allogeneic cells administered to relapsed GBM patients.

If the initial safety cohort establishes the safety of this modality, two cohorts of patients with either relapsed disease or newly diagnosed disease (as represented in Figure 24 below) will receive allogeneic gamma-delta cells. The primary goal of INB-400 is therefore threefold. First, it will establish the safety of allogeneic, genetically modified gamma-delta T cells. Second, it will assess the efficacy of these cells in treating patients with relapsed GBM and finally, it will assess the relative benefit and risk of treating newly diagnosed GBM patients with either allogeneic or autologous genetically modified gamma-delta T cells. While allogeneic product is likely to have more anti-tumor activity, the clinical activity noted with autologous product needs further elaboration. In addition, the value of an autologous product lies in the paucity of donors for all patients. Given our experience with INB-100 and available preclinical data, we expect a low rate of GvHD but given the novelty of intracranial delivery of allogeneic cells, the company intends to modulate risk by also continuing development of the autologous product which appears to have manageable safety and evidence of clinical activity. Nevertheless, given the updated guidance from the FDA to submit separate INDs for different versions of cell therapy, the company will initially submit an IND consisting of the autologous product in the second half of 2022 with a supplemental IND supporting the allogeneic product shortly thereafter.

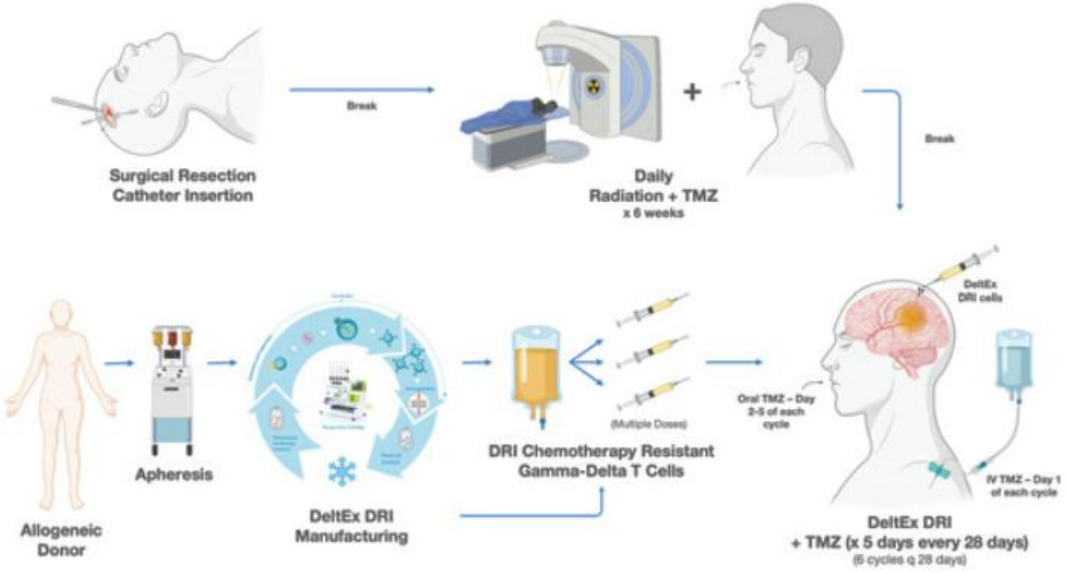

Figure 24. INB-400 Allogeneic Administration

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. While we have developed a classical signaling CAR-T construct which is cytotoxic, we have also designed a novel non-signaling chlorotoxin CAR-T construct that omits CD3z. This non-signaling CAR allows the modified gamma-delta cells to better traffic to the tumor cells expressing the chlorotoxin receptor but maintains their endogenous receptors that recognize cellular stress ligands. This enables the cells to utilize their full range of antitumor killing receptors to recognize and kill tumor cells, rather than over-riding these functions and restricting them to recognizing a single antigen transmitted through the CAR, which is typical in a classical signaling CAR. This non-signaling strategy also incorporates a significant safety advantage in that off-target chlorotoxin-CAR binding of cells that were not expressing high levels of NKG2D or TCR, i.e., healthy normal tissue, would not result in activated cell killing and thus avoid an unintended cytotoxic response.

Additionally, this CAR construct also incorporates the gene for MGMT from INB-200, our DeltEx DRI candidate, as shown in Figure 25 below. This CAR-T construct is designed to confer both TMZ- resistance and tumor-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 are capable of serial killing of cancer cells, generated synergies with significantly greater CD69 activation than expected from the activity of a single chlorotoxin domain as well as increased persistence. We have demonstrated we can

transduce the MGMT-chlorotoxin-CAR into gamma-delta T cells and have documented CAR-T expression. We are currently testing these constructs in animal models and examining their utility for both local and systemic delivery for the treatment of solid tumors.

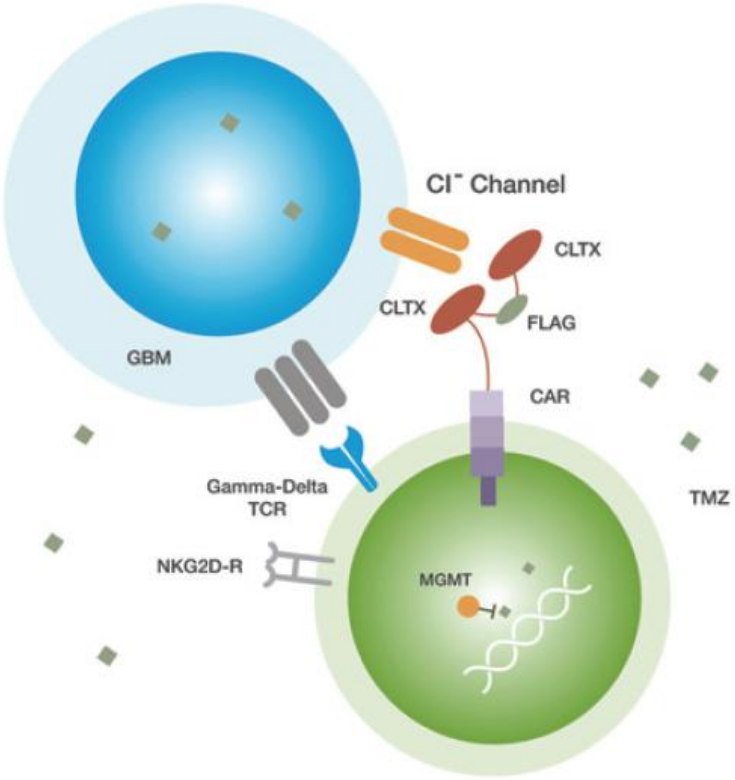

Figure 25. INB-300, a DeltEx DRI, Dual Chlorotoxin (CLTX) CAR

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 manufacturers and/or facilities for future production. We are analyzing the feasibility and costs 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 better-funded 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.

The field of gamma-delta T cells is growing rapidly. Our competitors in the field of gamma-delta T cell therapy include Acepodia USA, American Gene Technologies International Inc., Century Therapeutics, Inc., CytoMed Therapeutics Pte Ltd, Editas Medicine, Inc., Enochian BioSciences, Inc., ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Kiromic Biopharma, Inc., Lava Therapeutics B.V., Leucid Bio Ltd, PhosphoGam Inc., Sandhill Therapeutics, Inc. and Shattuck Labs, Inc. all of which remain preclinical. Five competitors, Adicet Bio, Inc., Avalon Globocare Corp., Gadeta BV, Takeda Pharmaceuticals USA, Inc. 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 resources and infrastructure including larger research and development staffs, infrastructure to support testing, developing, marketing and commercialization of products. 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 December 31, 2021, we owned, co-owned or exclusively licensed two issued U.S. patents, three issued European patents, one allowed patent application in Europe, one issued patent in Australia, one issued patent in Israel, one allowed patent application in New Zealand, eight pending U.S. applications, and 47 other foreign national-stage applications, including five 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 gamma-delta 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, three issued European patents (each which have been widely validated in Europe) 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, one allowed New Zealand patent application, and eight 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 co-own one pending U.S. patent application and nine other foreign national stage applications with The UAB Research Foundation 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 biologics license application, or 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 post-marketing 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 life-threatening 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.

Regenerative medicine advanced therapy, or RMAT, designation is intended to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies 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.

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.

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.

In the ordinary course of our business, we may process personal data or sensitive information. Accordingly, we may be subject to data privacy and security obligations, including federal, state, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, or CCPA, the Canadian Personal Information Protection and Electronic Documents Act, or PIPEDA, the European Union's General Data Protection Regulation 2016/679, or EU GDPR, and the EU GDPR as it forms part of United Kingdom law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act and Colorado passed the Colorado Privacy Act.

For example, 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), other healthcare professionals (such as physician assistants and nurse practitioners), 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. 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 data. For example, the California Consumer Privacy Act of 2018, or CCPA, provides new data privacy rights for consumers and new operational requirements for companies. Under the CCPA, covered businesses must provide specific disclosures related to a business's collection, use, and disclosure of personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties (of up to $7,500 per violation) and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law.

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 EU GDPR including, where relevant, as implemented in the United Kingdom, the UK GDPR. The

EU 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 information. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. 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 third-party 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 Cuts and Jobs Act of 2017, or 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated 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 instructed 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, 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, the reductions will stay in effect through 2031, other than a temporary suspension from May 1, 2020 through May 31, 2022 due to the ongoing COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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, Presidential executive orders 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. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Congress is also considering drug pricing as part of other health reform 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.

Human Capital

As of December 31, 2021, we had 19 full-time employees, of whom 13 were primarily engaged in research and development activities. A total of seven 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 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.

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 350 5th Avenue, Suite 5330, New York, New York 10118, 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 Annual Report on Form 10-K. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

Available Information

Our website address is www.in8bio.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors.

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

Summary of Selected Risk Factors Associated with Our Business

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

- We 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 have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We 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.
- Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our DeltEx products candidates utilize novel approaches to cell therapies, including cancer treatment, which presents significant challenges to successfully develop, manufacture and commercialize our product candidates.
- The clinical and commercial utility of our DeltEx platform is uncertain and may never be realized. Additionally, certain aspects of the function and production of gamma-delta T cells are poorly understood or currently unknown, and may only become known through further preclinical and clinical testing.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The ongoing COVID-19 pandemic, and other geopolitical tensions, such as Russia's recent incursion into Ukraine, could adversely impact our business, including our clinical trials, supply chain and business development activities.
- We face significant competition, and many of our competitors have substantially greater experience and resources than we have.
- Our manufacturing process is complex, and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for future clinical trials or commercialization, if approved.
- Clinical product candidate development involves a lengthy and expensive process and involve uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- If we encounter difficulties in enrolling patients with our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We currently store our gamma-delta T cells at our research and development facility and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise, would cause delays in replacement, and our business could suffer.
- We are currently dependent on a single third-party supplier for manufacture of our automated manufacturing device and our lentiviral vectors. 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, our clinical trials 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.
- Our ability to compete in the pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, and other personnel. The loss of the services of our key employees could impede, delay or prevent the successful development of our product pipeline, the completion of our current and planned clinical trials, and the commercialization of our products or in-licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.
- Actual or perceived failures to comply with applicable data privacy and security obligations, including laws, regulations, standards and other requirements could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

Risks Related to Our Financial Position and Capital Needs

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

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

- the timing, progress, costs and results of our ongoing preclinical studies and clinical trials of our product candidates, including accounting for any COVID-19-related delays or other related impacts on our development programs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, reimbursement and distribution, for any of our product candidates for which we may receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we may receive marketing approval;
- the cost of any milestone and royalty payments with respect to any approved product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval in order to generate revenue from product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, inflation expectations, 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 geopolitical tensions, such as Russia's recent incursion into Ukraine. 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.

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

We have incurred significant operating losses since inception. Our net loss was $14.7 million and $8.6 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $32.7 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. As inflation expectations increase in the United States and globally, we expect the costs of certain activities will increase. Should suppliers and consultants increase prices to cover increased wages and materials costs, we expect our expenses and cash utilization could increase substantially. We may never succeed in these activities and, even if we do, may never generate revenues that are sufficient to offset our expenses and achieve profitability.

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

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

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.

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 including the failure to demonstrate comparability or equivalence, these could impact the development plans for our other product candidates. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates could adversely affect our business, financial condition and results of operations.

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

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. INB-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 and/or product candidate will generate the same results or otherwise provide adequate data to demonstrate the efficacy, safety and equivalency of a product candidate. Preclinical studies and Phase 1 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or even if they successfully advance through earlier clinical trials.

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.

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

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

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

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

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

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

and consistent manner. As such, we may be faced with unforeseen results, delays and setbacks, in addition to the other foreseeable risks and uncertainties associated with developing immune cell therapies.

Additionally, we are the first company to advance a genetically modified gamma-delta T cell product candidate, INB-200, 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 lentiviral vector and/or 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, equivalency, purity and potency sufficient to enable the FDA to approve our DeltEx platform product candidates for any indication. This may be because early clinical trials do not meet their endpoints, because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the results of such trials are not statistically significant, because the FDA disagrees with how we interpret the data from these clinical trials, or because the FDA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. For example, we are developing INB-100 for the treatment of patients undergoing hematopoietic stem cell transplantation for the treatment of hematological malignancies, and our manufacturing process is predominantly based on cells received from healthy haploidentical related donors with at least half of the major human leukocyte antigen, or HLA, types matched. Our clinical development plan for INB-100 will seek to determine the safety of HLA mismatched, donor-derived gamma-delta T cells and establish the risk of graft versus host disease, or GvHD, if any. We will also seek to better understand the persistence of mismatched gamma-delta T cells and their potential impact on immune reconstitution, clinical activity and duration of response. While we have observed some grade 1 /2 GvHD that has been responsive to steroids treatment, we believe that a high degree of HLA matching will not be required to prevent or reduce the risks of GvHD or for clinically meaningful activity and durability of response, if it becomes apparent through preclinical testing or clinical trials that such matching is required, an allogeneic or an “off-the-shelf” product may not be attainable, which would prevent the further advancement of our INB-100 allogeneic product candidate and adversely affect our business and current development plans. We will also need to demonstrate that our DeltEx platform product candidates are safe. We do not have data on possible harmful long-term effects of our DeltEx platform product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and efficacy data sufficient to support submission of a marketing application or commercialization of our DeltEx platform product candidates is uncertain and is subject to significant risk.

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

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

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

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

A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our ongoing Phase 1 trials for INB-200 and INB-100 involve studying a relatively small patient population, which makes it difficult to predict whether the favorable results observed in such clinical trial will be repeated in larger and more advanced clinical trials.

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

- delays in reaching a consensus with regulatory authorities on the design, location or implementation of our clinical trials;
- delays or setbacks in patient enrollment;
- clinical trials of our product candidates may produce negative or inconclusive results;

- the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients that meet the study criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- the impact of the ongoing COVID-19 pandemic, which may slow potential enrollment, impact hospital clinical and/or administrative support staff, reduce the number of eligible patients for clinical trials, or reduce the number of patients that remain in our trials;
- imposition of a clinical hold by regulatory authorities as a result of, among other reasons, a serious adverse event, a failure in the chemistry manufacturing and controls requirements, or a failed inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- need to conduct additional clinical trials or abandon product development programs.

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

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

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

Additionally, the FDA or an independent 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 and INB-400, to be used in combination with approved therapies, such as chemotherapy, which may present additional challenges. For example, the FDA may require us to use more complex clinical trial designs, to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that most or any positive results are attributable to the already approved product. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross-labeled. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement. Moreover, developments related to the already approved therapies may impact our clinical

trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the approved therapy's safety or efficacy profile, changes to the availability of the approved therapy, and changes to the standard of care.

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

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

- the size and nature of the patient population;
- the severity and incidence of the disease under investigation;
- the design of the trial and the complexity for patients and clinical sites;
- the general health condition of the patient and their gamma-delta T cells and immune cells broadly;
- the risk that patients' general health conditions do not allow the conduct of study/screening procedures (such as leukapheresis) the manufacture of therapeutic product or application of the appropriate standard-of-care treatment or application of the Stupp regimen;
- the ability to consistently manufacture gamma-delta T cell product candidates in sufficient quantities at sufficient activity and/or transduction efficiency to provide a suitable therapeutic dose of gamma-delta T cells;
- competing clinical trials for similar therapies, other new therapeutics, new combination treatments, new medicinal products;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved or become standard of care for the indications we are investigating;
- the ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients' unwillingness to participate due to the ongoing COVID-19 pandemic;
- the risk that enrolled subjects will drop out, develop complications or die before completion of the trial;
- the ability to develop and provide appropriate screening, product characterization and release assays;
- patients failing to complete a clinical trial or returning for post-treatment follow-up;
- our ability to manufacture the requisite materials for a patient and clinical trial; and
- inability of clinical sites to enroll patients as health care capacities are required to cope with natural disasters, epidemics or other health system emergencies, such as the evolving and ongoing COVID-19 pandemic.

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

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

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

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

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

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

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

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

In connection with the ongoing COVID-19 pandemic, governments have implemented significant measures, including closures of businesses, quarantines, travel restrictions and other social distancing directives, intended to control the spread of the virus. Companies have also taken precautions, such as requiring employees to work remotely, imposing travel restrictions and temporarily closing businesses. In response to these public health directives and orders, we have implemented certain travel restrictions and work-from-home policies for our employees, and as a result we have experienced limitations on employee resources. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19

may negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, may cause disruptions to our supply chain, to the administrative functions of clinical trial sites and/or to the operations of our other partners, and as a result may impair our ability to execute our programs and/or business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, including our laboratories and our operations may be further limited or curtailed.

Our clinical trials have been, and may in the future be, affected by the ongoing COVID-19 pandemic. If a patient in any of our clinical trials contracts COVID-19, it could cause a serious adverse event to occur, especially in light of the immunosuppressive conditioning to which such patients are subject. In the past, 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 again in the future result in significant delays to our clinical trials. In addition, due to the ongoing COVID-19 pandemic we had previously been required to submit to the FDA and the IRB a modified clinical protocol to mitigate the risks associated with COVID-19 exposure. This potentially could result in lower product potency but allow for the confirmation of a negative COVID-19 result prior to initiating the conditioning and/or myeloablation of the patient. While the impact of COVID-19 has waned since the passing of the Omicron variant in early 2022, we expect infections could again increase in the South during the summer months and throughout the country again late next fall. We may experience other disruptions due to the ongoing COVID-19 pandemic that could severely impact our business, preclinical studies and clinical trial, 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, increases in inflation expectations, 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.

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 to identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

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

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

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or 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 and a recent increase in patient deaths and clinical holds by other companies, could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Negative public attitudes may adversely impact our ability to enroll

patients in clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target 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 immuno-oncology, is highly competitive. We may face potential competition with respect to our current product candidates and may face competition with respect to any other product candidates that we may seek to develop or commercialize in the future from pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research institutions.

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

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

The Biologics Price Competition and Innovation Act of 2009, 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-party contractors or contract development manufacturing organization for the manufacturing of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.

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

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

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

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

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

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

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

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

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

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

We currently store our biologic correlative and research specimens from clinical trials and development programs and clinical lentivectors at our research and development facilities, and any damage or loss to our storage freezers would cause delays in replacement, and our business could suffer.

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

We are currently dependent on a single third-party supplier for manufacture of our automated manufacturing device and our lentiviral vectors. 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, cell-manufacturing, closed system device. We have multiple devices, including backup devices in all facilities if the primary instrument breaks, however, if the devices are damaged and cannot be repaired or the supplier cannot deliver new devices in a timely manner, or at all, our ability to manufacture and supply sufficient quantities of our products for clinical or commercial usage could be delayed, or potentially hindered. In addition, there is currently a significant backlog for lentiviral vector manufacturing due to increased demand. Our current supply of vectors will only cover approximately 29 patients. If our third-party contractor is unable to provide adequate lentiviral vectors in a timely manner, our ability to manufacture and supply sufficient quantities of our product candidates for clinical or commercial usage will be delayed or hindered, and our business could suffer.

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

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

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

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

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

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

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

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

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

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

Although we are conducting our current Phase 1 clinical trials through our direct contractual agreements with hospitals, we intend to rely on CROs and clinical trial sites to conduct our future preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of the activities of our third-party service providers, including investigators and CROs. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

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

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

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

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

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

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

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

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

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

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

The ability of the FDA to review and approve new products or regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events, such as the ongoing COVID-19 pandemic, that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the ongoing COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities and has resumed certain on-site inspections 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. Regulatory authorities outside the United States have adopted 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 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 note 10 in our condensed financial statements, “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 December 31, 2021, we owned, co-owned or exclusively licensed two issued U.S. patents, three issued European patents, one allowed patent application in Europe, one issued patent in Australia, one issued patent in Israel, one allowed patent application in New Zealand, eight pending U.S. applications, and 47 other foreign national-stage applications, including five European regional-phase applications that are important to the development of our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property, trademarks and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, names, including interference proceedings, post grant review and *inter partes* review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party

patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Other companies and research institutions have filed, and may file in the future, patent applications related to gamma-delta T cell immunotherapy. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

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

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

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

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

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

property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further,

we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

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

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

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

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

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

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

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

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

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

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

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we currently only maintain “key person” life insurance for our President and Chief Executive Officer.

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

As of December 31, 2021, we had 19 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.

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

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, share, and transmit proprietary, confidential, and sensitive data, including but not limited to, personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such sensitive 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 sensitive information. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place.

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

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us. 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. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

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 incidents that may remain undetected for an extended period. If any of the previously identified or similar threats 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, 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.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. 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. Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

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

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

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

Under current U.S. federal tax law, NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely, but the 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 carryforward/carryback periods, any limitations on use of NOLs, and any other changes in applicable law relating to NOLs through new legislation, regulations or other guidance, 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 federal law. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase the state taxes owed.

In order to realize the future tax benefits of our NOL carryforwards, we must generate taxable income, of which there is no assurance. Accordingly, we have provided a full valuation allowance for deferred tax assets as of December 31, 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 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 such as Russia's recent incursion into Ukraine, 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated 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 instructed 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, 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, 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. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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, Presidential executive orders 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. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Congress is also considering drug pricing as part of other health reform 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 privacy and security obligations, including laws, regulations, standards and other requirements could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations governing the processing of personal data and other sensitive information, 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 process sensitive information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of sensitive information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we 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 (i.e., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal data 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 data privacy and security requirements under HIPAA 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 data privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, California enacted the CCPA, which gives California residents expanded rights. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. Further, it is anticipated that the California Privacy Rights Act, or CPRA, effective January 1, 2023, will expand the CCPA. It will also create a new California Privacy Protection Agency authorized to issue substantive regulations and enforce the CPRA, which could result in increased

privacy and information security enforcement. Other states have enacted data privacy laws as well. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

In addition, all 50 U.S. states and the District of Columbia have enacted breach notification laws that may require us to notify 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. 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.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. In Canada, the PIPEDA and various related provincial laws, may apply to our operations.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses, or SCCs. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. 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.

In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection, and certain countries outside Europe (i.e. Russia) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business.

If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

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. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, or adversely affect our business and results of operations. For example, we may experience adverse consequences such as interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations; government enforcement actions (i.e., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Risks Related to the Ownership of Our Common Stock

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

Prior to our IPO in August 2021, there had not been a public market for our common stock. The liquidity in our common stock remains thin, while broader markets have experienced significantly increased volatility due to increases in inflation expectations and the recent Russian incursions into Ukraine. If an active trading market for our common stock does not develop, you may not be able to sell your shares quickly or at all at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

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

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

- the commencement, enrollment or results of our planned or future clinical trials of our product candidates or those of our competitors;
- the success and failures of competitive products or therapies or announcements, including patient deaths and clinical holds, by potential competitors of their product development efforts;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- coordinated buying or selling activity in our common stock, including market manipulation;
- unusual trading in our common stock or securities derivative thereof, including pursuant to naked, or uncovered, short positions or “short squeezes;”
- commentary by investors on the prospects for our business or our common stock on the internet, including blogs, articles and message board, and/or social media and resulting in trading of our common stock;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- market volatility due to the continued effects of and responses to the ongoing COVID-19 pandemic and Russia's recent incursion into Ukraine;
- economic weakness, including inflation, in particular economies and markets;

- stock price and volume fluctuations attributable to inconsistent trading volume levels and a wide bid-ask in our common stock;
- announcement or expectation of additional financing efforts or sales by our stockholders;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including due to Russia's recent incursion into Ukraine; 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 December 31, 2021, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock will, in the aggregate, beneficially own shares representing 70.5% of our outstanding common stock. If our executive officers, directors and stockholders who own more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital, if available, through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

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

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

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

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

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- provide that our directors may be removed for cause only upon the vote of at least 66⅔% of our outstanding shares of voting stock;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock; and
- require the approval of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

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

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

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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

General Risk Factors

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

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 3,900 square feet of office space for our principal executive offices in New York, New York, under an operating lease that expires on February 28, 2027, with no renewal 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 in Birmingham, Alabama, under an operating lease that currently expires on September 1, 2022, which can be terminated by us upon 60 days' notice and has an option for a five-year extension. We have also leased approximately 9,000 square feet of space located in the Martin Biscuit Building in Birmingham, Alabama. The lease is a 63-month term, expiring on February 17, 2026 and has an option for a five-year extension. We are developing approximately 5,250 square feet of this space as laboratory space, as well as approximately 3,700 square feet as office and conference space. 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.

Item 3. 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 an adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on The Nasdaq Stock Market LLC under the symbol "INAB" on July 30, 2021. Prior to that time, there was no public market for our common stock.

Holders

As of March 10, 2022, there were approximately 50 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from the IPO

On August 3, 2021, we completed our IPO in which we issued and sold 4,000,000 shares of our common stock at a public offering price of $10.00 per share pursuant to its Registration Statement on Form S-1, as amended (File No. 333-249530). We received net proceeds from the initial public offering of $32.3 million, after deducting underwriters' discounts, commissions and estimated offering-related costs. B. Riley Securities Inc. acted as the sole book-running manager for the IPO.

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

There has been no material change in the planned use of proceeds from the IPO from those disclosed in the Registration Statement. As of the date of this Annual Report on Form 10-K, we have not used any of the proceeds from the IPO.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer. Gamma-delta T cells are naturally occurring immune cells that embody properties of both the innate and adaptive immune systems and can intrinsically differentiate between healthy and diseased tissue. These cells serve as a functional bridge between innate and adaptive immunity to contribute to direct tumor killing, as well as immune cell recruitment and activation to drive deeper immune responses. The pivotal role of gamma-delta T cells in immune function and activation, against diseases such as cancer, underscores their therapeutic potential across a wide range of solid and hematologic malignancies. We develop *ex vivo*-expanded and activated gamma-delta T cell candidates based upon our deep expertise in gamma-delta T cell biology, proprietary genetic engineering and cell-type specific manufacturing capabilities, which we refer to collectively as our DeltEx platform. Our platform employs allogeneic, autologous and genetically modified approaches to advance 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 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 high-risk leukemias that are undergoing hematopoietic stem cell transplantation, or HSCT. For INB-200, we expect to report initial topline Phase 1 clinical trial results in the second half of 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, we plan to initiate a new Phase 1b/2 clinical program INB-400 in which both allogeneic and autologous genetically modified gamma-delta T cells will be assessed in both relapsed and newly diagnosed GBM patients. A portfolio of preclinical programs, including INB-300, focused on addressing various solid tumors using a dedicated gamma-delta chimeric antigen receptor T cell, or CAR-T cell, construct is also in progress. We will continue to advance internal research, including advancing manufacturing approaches and the application of our proprietary DeltEx DRI approach into additional solid tumor indications. We expect to file several INDs for our pipeline product candidates through 2023, with the first IND expected to be filed by the second half of 2022.

On August 3, 2021, we completed our IPO, whereby we issued and sold 4,000,000 shares of our common stock at a price to the public of $10.00 per share for aggregate gross proceeds of $40.0 million. We received approximately $32.3 million in net proceeds after deducting underwriting discounts, commissions and offering expenses.

Since inception in 2016, our operations have focused on identifying and developing potential product candidates, conducting clinical trials, organizing and staffing the Company, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations primarily through the sale of equity and equity-linked securities. Through December 31, 2021, we raised an aggregate of $75.6 million of gross proceeds from the sale of our securities, including through our IPO.

We have incurred significant operating losses since our inception. Our net losses were $14.7 million and $8.6 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $32.7 million. We expect our expenses and operating losses will increase substantially for the foreseeable future as we advance our product candidates through clinical trials, seek to expand our product candidate portfolio through developing additional product candidates, grow our clinical, regulatory and quality capabilities, and incur additional costs associated with operating as a public company. 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. If we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

Impact of COVID-19

The ongoing COVID-19 pandemic, including the periods of resurgences of cases relating to the spread of various strains such as the Delta and Omicron variants, has had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and productions have been suspended. The COVID-19 pandemic has impacted and may continue to impact the clinical sites and startup activities for our Phase 1/2 clinical trial, including third-party manufacturing and logistics providers, which have disrupted and may continue to disrupt its clinical supply chain and the availability or cost of materials, and it has affected and may continue to affect the Company's ability to timely initiate, enroll and complete its clinical trials, conduct regulatory activities and operate its business more generally. The pandemic may impact the timing of regulatory approval of the investigational new drug application for clinical trials, the enrollment of any clinical trials that are approved, the availability of clinical trial materials and regulatory approval and commercialization of our products. The pandemic may also impact the capital markets, inflation expectations and the Company's ability to access capital, which could negatively impact short-term and long-term liquidity. The extent to which the COVID-19 pandemic will directly or indirectly continue to impact our business, results of operations, financial condition and liquidity, including ongoing and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of evolving variants of COVID-19, the actions taken to contain or treat it, including the likelihood of achieving widespread global vaccination rates, the duration and intensity of the related effects of the pandemic and the uncertainty of the timing of the broader economic recovery to pre-pandemic levels.

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 Expense

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

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

Income Taxes

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

Results of Operations

Comparison of the years ended December 31, 2021 and 2020

The following sets forth our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 7,347	$ 5,378	$ 1,969
General and administrative	7,306	3,179	4,127
Total operating expenses	14,653	8,557	6,096
Loss from operations	(14,653)	(8,557)	(6,096)
Net loss	$ (14,653)	$ (8,557)	$ (6,096)

Research and Development Expenses

Research and development expenses were $7.3 million and $5.4 million for the years ended December 31, 2021 and 2020, respectively. The increase of $1.9 million was primarily due to increased third-party clinical trial-related activities and contract manufacturing costs for the ongoing INB-200 clinical trial and increased personnel related costs, including salaries, benefits and stock-based compensation due to increased headcount.

General and Administrative Expenses

General and administrative expenses were $7.3 million and $3.2 million for the years ended December 31, 2021 and 2020, respectively. The increase of $4.1 million was primarily due to increased personnel costs, including salaries, benefits and stock-based compensation due to increased headcount and increased legal expenses related to the IPO, insurance and activities as a public company.

Liquidity and Capital Resources

Overview

As of December 31, 2021, we had cash of $37.0 million. To date, we have funded our operations primarily through the sale of equity and equity-linked securities. Through December 31, 2021, we have raised an aggregate of $75.6 million of gross

proceeds from the sale of our securities, including through our IPO. We believe that our cash, cash equivalents and short-term investments as of December 31, 2021, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

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.

Funding Requirements

We believe that our available cash is sufficient to fund existing and planned cash requirements. 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. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses and general overhead costs.

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

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- addressing any potential interruptions, delays and/or cost increases resulting from factors related to the ongoing COVID-19 pandemic, and other geopolitical tensions, such as Russia's recent incursion into Ukraine;
- economic weakness, including inflation, or political instability in particular economies and markets;
- 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.

Since inception, we have not generated any product revenue and have incurred net losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all. It is likely that we will seek third-party collaborators for the future commercialization of our product candidates that are approved for

marketing. However, we may seek to commercialize our products at our own expense, which would require us to incur significant additional expenses for marketing, sales, manufacturing and distribution.

Until such time as we can generate significant revenue from product sales, if ever, we expect to 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, increases in inflation expectations 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 other geopolitical tensions, such as Russia's recent incursion into Ukraine. 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.

Material Cash Requirements

The following table summarizes our contractual obligations and commitments as of December 31, 2021:

		Payments Due by Period			
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
		(in thousands)			
Operating lease commitments	$ 2,231	$ 405	$ 1,470	$ 356	$ —
Financing lease commitments	717	435	282	—	—
Total	$ 2,948	$ 840	$ 1,752	$ 356	$ —

In addition, we entered into a lease agreement with a third party to build out our labs in Birmingham, Alabama for an aggregate expected cost of $4.0 million. As of December 31, 2021, $0.2 million in expenses have been incurred. For more information on the lease agreement, see Note 14 of our financial statements.

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.

Cash Flows

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

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (13,509)	$ (7,133)
Net cash used in investing activities	(309)	—
Net cash provided by financing activities	32,955	24,517
Net increase in cash	$ 19,137	$ 17,384

Operating Activities

Cash used in operating activities was $13.5 million during the year ended December 31, 2021, primarily due to our net loss of $14.7 million and decreases in our accrued expenses and other current liabilities along with prepaid expenses mainly due to

lower legal accruals and prepayments as a result of the completion of the IPO, partially offset by $2.2 million in stock-based compensation due to increased employee headcount resulting from growth in our business.

Cash used in operating activities was $7.1 million during the year ended December 31, 2020, primarily due to our net loss of $8.6 million offset by increases in our operating assets and liabilities of $0.6 million and increases in non-cash charges of $0.8 million. Increases in our operating assets and liabilities consisted primarily of $0.8 million in accrued expenses and other current liabilities due to increased legal expenses related to preparing for the IPO. Increases in our non-cash charges consisted primarily of $0.4 million in stock-based compensation due to higher employee headcount as the Company expanded.

Investing Activities

Cash used in investing activities was $0.3 million during the year ended December 31, 2021, primarily due to construction in progress activity in relation to leasehold improvements to the Alabama leased space.

Financing Activities

Cash provided by financing activities was $33.0 million during the year ended December 31, 2021, primarily due to proceeds received from the issuance and sale of common stock in our IPO.

Cash provided by financing activities was $24.5 million during the year ended December 31, 2020, primarily due to the issuance of Series A convertible preferred stock.

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

Critical Accounting Policies

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. Our significant accounting policies are more fully described in Note 2 to our financial statements located in "Part I – Financial Information, Item 1. Financial Statements" in this Annual Report on Form 10-K. We have listed below our critical accounting estimates that we believe to have the greatest potential impact on our financial statements. Historically, our assumptions, judgments and estimates relative to our critical accounting estimates have not differed materially from actual results.

Research and Development Costs

We expense all costs incurred in performing research and development activities. Research and development expenses include salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and entities that conduct certain research and development activities on 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 an 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 an expense over the requisite service period which is generally the vesting period. In the periods prior to the IPO, the determination of fair value of our common stock required significant judgment. In the periods following the IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

Prior to our IPO, there was no public market for our common stock, and consequently, the estimated fair value of our common stock was determined by our Board of Directors as of the date of each option grant, 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 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.

Emerging Growth Company and Smaller Reporting Company Status

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

We may take advantage of these exemptions until December 31, 2026 or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

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

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates was less than $700 million at the closing of the IPO and our annual revenue for 2020 was less than $100 million. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

Our financial statements required by this item, together with the report of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report on Form 10-K.

INDEX TO FINANCIAL STATEMENTS

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, 2021 and 2020, and the related statements of operations, convertible preferred stock, common stock and stockholders' equity (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, 2021 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.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases as of January 1, 2021 due to the adoption of Financial Accounting Standards Board Accounting Standard Codification Topic 842, *Leases*.

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 the 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 audit to obtain reasonable assurance about whether the financial statements are free from 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 2017

Tysons, Virginia
March 17, 2022

IN8BIO, INC.
Balance Sheets
(In thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash	$ 37,021	$ 17,994
Prepaid expenses and other current assets	1,959	150
Total Current Assets	38,980	18,144
Non-current assets		
Property and equipment, net	97	186
Construction in progress	403	—
Restricted cash	251	141
Deferred offering costs	—	2,439
Right of use assets - financing leases	704	—
Right of use assets - operating leases	1,630	—
Other non-current assets	158	—
Total Non-Current Assets	3,243	2,766
Total Assets	$ 42,223	$ 20,910
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Liabilities		
Current liabilities		
Accounts payable	$ 395	$ 620
Accrued expenses and other current liabilities	1,235	1,778
Short-term financing lease liability	392	—
Short-term operating lease liability	234	—
Loan payable, current	—	174
Total Current Liabilities	2,256	2,572
Deferred rent	—	17
Long-term financing lease liability	269	—
Long-term operating lease liability	1,515	—
Total Non-Current Liabilities	1,784	17
Total Liabilities	4,040	2,589
Commitments and Contingencies		
Convertible preferred stock, Series A (Note 8)	—	34,900
Stockholders' Equity (Deficit)		
Common stock, par value $0.0001 per share; 490,000,000 and 50,700,000 shares authorized at December 31, 2021 and 2020, respectively; 18,781,242 and 3,764,488 shares issued and outstanding at December 31, 2021 and 2020, respectively	2	1
Additional paid-in capital	70,872	1,458
Accumulated deficit	(32,691)	(18,038)
Total Stockholders' Equity (Deficit)	38,183	(16,579)
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)	$ 42,223	$ 20,910

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

IN8BIO, INC.
Statements of Operations
(In thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Operating expenses:		
Research and development	$ 7,347	$ 5,378
General and administrative	7,306	3,179
Total operating expenses	14,653	8,557
Loss from operations	(14,653)	(8,557)
Net loss	$ (14,653)	$ (8,557)
Net loss attributable to common stockholders (Note 12)	$ (14,653)	$ (10,340)
Net loss per share attributable to common stockholders – basic and diluted	$ (1.47)	$ (3.02)
Weighted-average number of shares used in computing net loss per common share – basic and diluted	9,969,733	3,419,075

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

IN8BIO, INC.
Statements of Convertible Preferred Stock, Common Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
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 – in relation to license agreement	—	—	89,629	—	103	—	103
Issuance of common stock – 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 costs	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)
Issuance of common stock – as a result of IPO, net of issuance costs of $7,685	—	—	4,000,000	—	32,290	—	32,290
Conversion of convertible preferred stock to common stock upon closing of IPO	(9,993,727)	(34,900)	10,990,065	1	34,899	—	34,900
Stock options exercises	—	—	26,689	—	30	—	30
Stock-based compensation expense	—	—	—	—	2,195	—	2,195
Net loss	—	—	—	—	—	(14,653)	(14,653)
Balance at December 31, 2021	—	$ —	18,781,242	$ 2	$ 70,872	$ (32,691)	$ 38,183

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

IN8BIO, INC.
Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2021	**2020**
Operating activities		
Net loss	$ (14,653)	$ (8,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	89	88
Stock-based compensation	2,195	357
Stock issuance related to license agreement	—	103
Stock issuance related to legal settlement	—	248
Deferred rent	—	17
Amortization of financing lease right-of-use assets	537	—
Amortization of operating lease right-of-use assets	162	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,876)	3
Other non-current assets	(159)	(48)
Accounts payable	(319)	(160)
Accrued expenses and other current liabilities	554	816
Short-term operating lease liabilities	158	—
Long-term operating lease liabilities	(197)	—
Net cash used in operating activities	(13,509)	(7,133)
Investing activities		
Construction in progress	(309)	—
Net cash used in investing activities	(309)	—
Financing activities		
Proceeds from exercise of common stock options	30	13
Proceeds from the issuance of common stock	36,327	499
Proceeds from issuance of preferred stock - net of $81 of issuance costs	-	25,175
Principal payments on financing leases	(535)	—
Proceeds from issuance of loan	-	174
Repayment of loan payable	(174)	—
Payment of deferred offering costs	(2,693)	(1,344)
Net cash provided by financing activities	32,955	24,517
Net increase in cash and restricted cash	19,137	17,384
Cash and restricted cash at beginning of year	18,135	751
Cash and restricted cash at end of year	$ 37,272	$ 18,135
Supplemental disclosure of non-cash operating, financing and investing information:		
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,095
Exercise of convertible preferred stock warrants	$ —	$ 829
Construction in progress included in accounts payable	$ 94	$ —
Conversion of preferred stock - Series A into common stock	$ 34,900	$ —
Right-of-use assets obtained in exchange for financing lease	$ 309	$ —
Right-of-use assets obtained in exchange for operating lease	$ 969	$ —
Initial measurement of lease right-of-use assets	$ 1,693	$ —
Initial measurement of lease liabilities	$ 1,728	$ —

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

IN8BIO, INC.
Statements of Cash Flows Continued
(In thousands)

The following table provides a reconciliation of cash and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statements of cash flows (in thousands):

	December 31, 2021	December 31, 2020
Cash, end of year	$ 37,021	$ 17,994
Long-term restricted cash, end of year	251	141
Cash and restricted cash, end of year	$ 37,272	$ 18,135

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

1. ORGANIZATION AND NATURE OF OPERATIONS

Organization and Business

IN8bio, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer. The Company's lead product candidates are currently in Phase 1 clinical trials: INB-200, for the treatment of patients with 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-300 and INB-400, focused on addressing other solid tumor types.

Incysus, Inc. ("Incysus") was a corporation formed in the State of Delaware on November 23, 2015 and Incysus, Ltd. was incorporated in Bermuda on February 8, 2016. Incysus was the wholly owned United States subsidiary of Incysus, Ltd. On May 7, 2018, Incysus, Ltd. reincorporated in the United States in a domestication transaction (the "Domestication") in which Incysus, Ltd. converted into a newly formed Delaware corporation, Incysus Therapeutics, Inc. ("Incysus Therapeutics"). On July 24, 2019, Incysus Therapeutics merged with Incysus. Incysus Therapeutics subsequently changed its name to IN8bio, Inc. in August 2020. Following the Domestication in May 2018 and the merging of Incysus Therapeutics and Incysus in July 2019, the Company did not have any subsidiaries to consolidate as of December 31, 2020. The Company is headquartered in New York, New York.

Coronavirus Pandemic

The ongoing COVID-19 pandemic, including the periods of resurgences of cases relating to the spread of various strains such as the Delta and Omicron variants, has had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and productions have been suspended. The COVID-19 pandemic has impacted and may continue to impact the clinical sites and startup activities for the Company's Phase 1/2 clinical trial, including third-party manufacturing and logistics providers, which have disrupted and may continue to disrupt its supply chains and the availability or cost of materials, and it has affected and may continue to affect the Company's ability to timely initiate, enroll and complete its clinical trials, conduct regulatory activities and operate its business more generally. The pandemic may impact the timing of regulatory approval of the investigational new drug application for clinical trials, the enrollment of any clinical trials that are approved, the availability of clinical trial materials and regulatory approval and commercialization of our products. The pandemic may also impact the capital markets, inflation expectations and the Company's ability to access capital, which could negatively impact short-term and long-term liquidity. The full extent to which the pandemic may impact the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including as a result of evolving variants of COVID-19, the actions taken to contain or treat it, including the likelihood of achieving widespread global vaccination rates, the duration and intensity of the related effects of the pandemic and the uncertainty of the timing of the broader economic recovery to pre-pandemic levels.

Initial Public Offering

On August 3, 2021, the Company completed its initial public offering ("IPO") in which it issued and sold 4,000,000 shares of its common stock at a public offering price of $10.00 per share. The Company received net proceeds from the IPO of $32.3 million, after deducting underwriters' discounts, commissions, and offering-related costs. Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 10,990,065 shares of common stock (see Note 8).

Liquidity and Capital Resources

Through December 31, 2021, the Company funded its operations primarily with proceeds from its Series A convertible preferred stock financing ("Series A Financing") and, with proceeds from its IPO. The Company has incurred recurring losses and negative operating cash flows from operations since its inception, including net losses of $14.7 million and $8.6 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had an accumulated deficit of $32.7 million.

The Company has not yet generated product sales and as a result has experienced operating losses since inception. The Company expects to incur additional losses in the future to conduct research and development and will need to raise additional capital to fully implement management's business plan. The Company intends to raise such capital through the issuance of

additional equity, and potentially through borrowings, strategic alliances with partner companies and other licensing transactions. However, if such financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Management believes that its existing cash of $37.0 million as of December 31, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance of these financial statements.

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 stock-based compensation, and accrued research and development costs. Management bases certain 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 $0.3 million in the form of cash collateral for the Company's letter of credit for the year ended December 31, 2021, which has been classified as restricted cash on the Company's balance sheet. The Company had restricted cash of $0.1 million in the form of a security deposit related to its agreement with an equipment rental company as of December 31, 2020, which has been classified as restricted cash on the Company's balance sheet.

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:

	Estimated Useful Life
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, 2021 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 research and development costs are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers.

Leases

Effective January 1, 2021, the Company adopted the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02" or "ASC 842"), using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under Accounting Standards Codification ("ASC") 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 $1.7 million was recognized as total right-of-use assets on the Company's balance sheet. Additionally, $0.04 was recognized as a reduction to

prepaid expenses and other current assets and $0.02 was recognized as a reduction to deferred rent on the Company's balance sheet.

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.

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, and accounts payable. 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 uses the asset-and-liability method for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts and tax bases of assets and liabilities and operating loss and tax credit carryforwards. These are measured using the enacted tax rates that are expected to be in effect when the differences reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to an amount that, in the opinion of management, is more likely than not to be realized.

The calculation of the income tax expense involves the use of estimates, assumptions and judgments while taking into account current tax laws and our interpretation of current and possible outcomes of future tax audits. In addition, our policy for accounting for uncertainty in income taxes requires the evaluation of tax positions taken or expected to be taken in the course of the preparation of tax returns to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet the more-likely-than-not threshold would be recorded as a tax expense in the current year. Reevaluation of tax positions considers factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit or expiration of statute of limitation and new audit activity. The Company classifies interest and penalty expense related to uncertain tax positions as a component of operating expenses on the statements of income. As of December 31, 2021, the Company had no accrued interest or penalties.

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 enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits 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 evaluated the impact of the CARES Act. At present, the Company does not expect that the NOL carryback provision or other provisions of the CARES Act resulting in a material tax benefit to the Company.

Convertible Preferred Stock Classification

The Company records all convertible preferred stock upon issuance at its respective fair value or original issuance price less issuance costs. The Company classifies its convertible preferred stock outside of stockholders' deficit as the redemption of such shares is outside the Company's control. The Company does not adjust the carrying values of the convertible preferred stock to redemption value unless and until it becomes probable that the instrument will become redeemable. As of December 31, 2020, the Company's convertible preferred stock was not adjusted to redemption value. After the closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into shares of common stock.

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 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.

Before the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation (the "Practice Aid"), to estimate the fair value of its common stock. The common stock valuation is based on the Company's enterprise value determined utilizing various methods including the option-pricing method ("OPM") or a hybrid of the probability-weighted expected return method ("PWERM") and the OPM. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

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. As of August 3, 2021, the date of the closing of the Company's IPO, the Company had deferred offering costs related to the IPO of $4.0 million. After closing of the IPO, these costs were recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering.

Recently Issued Accounting Standards Updates

In December 2019, the FASB Issued ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting of Income Taxes*," which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent

application. This guidance is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. The Company has evaluated this guidance and determined that it does not have a material impacts to its financial statements.

3. PROPERTY AND EQUIPMENT, NET

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

	December 31, 2021	December 31, 2020
Machinery and equipment	$ 443	$ 443
Less accumulated depreciation	(346)	(257)
Property and equipment, net	$ 97	$ 186

Depreciation expense was $0.1 million for the years ended December 31, 2021 and 2020.

4. CONSTRUCTION IN PROGRESS

Construction in progress consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Furniture	$ 77	$ —
Leasehold improvements	200	—
Internal use software not yet in service	126	—
Construction in progress	$ 403	$ —

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31, 2021	December 31, 2020
Accrued offering costs	$ —	$ 876
Accrued clinical trials	196	376
Accrued compensation	926	400
Accrued other	113	126
Total accrued expenses and other current liabilities	$ 1,235	$ 1,778

6. DEBT

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

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

In August 2021, the Company repaid the PPP Loan of $0.2 million in full.

7. STOCKHOLDERS' EQUITY (DEFICIT)

In August 2021, in connection with the IPO, the Company filed an Amended and Restated Certificate of Incorporation which authorized 490,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company’s Board of Directors in one or more series.

Common Stock

There were 490,000,000 shares and 50,700,000 shares authorized for issuance at December 31, 2021 and 2020, respectively, and 18,781,242 shares and 3,764,488 shares issued and outstanding at December 31, 2021 and 2020, respectively.

Convertible Preferred Stock

Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 10,990,065 shares of common stock. There were no outstanding shares at December 31, 2021.

As of December 31, 2020, there were 27,564,260 shares of convertible preferred stock authorized and 9,993,727 shares, issued and outstanding. The convertible preferred shares had a par value of $0.0001 and liquidation preference of $38.0 million.

Preferred Stock Warrants

As of December 31, 2021 and 2020, there were no preferred stock warrants outstanding. During the year ended December 31, 2020, all 231,396 outstanding warrants were exercised at the price of $0.0003 per share and the warrant liability was settled for the fair value of $0.8 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. Upon the effectiveness of the 2020 Plan (as defined below), the plan was terminated and no further issuances were made under the 2018 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2018 Plan.

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the “2020 Plan”) was approved by the Board of Directors and the Company’s stockholders and became effective on July 29, 2021. The Board of Directors, or committee thereof, is authorized to administer the 2020 Plan. The 2020 Plan provides for the grant of incentive stock options ("ISOs") within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended, to employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants and any affiliates’ employees and consultants. The number of shares initially reserved for issuance under the 2020 Plan was 4,200,000, which will automatically increase on January 1 of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the total number of shares of common stock outstanding on the last day of the immediately preceding year, or a lesser number of shares determined by the Board of Directors no later than the last day of the immediately preceding year. The maximum number of shares of common stock that may be issued upon the exercise of ISOs under the 2020 Plan will be 13,000,000 shares. As of December 31, 2021, 10,594,584 shares were available for grant pursuant to the Plan. On January 1, 2022, the shares reserved for issuance was increased to 5,139,062 shares.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the “2020 ESPP”) was approved by the Company’s Board of Directors and the Company’s stockholders and became effective on July 29, 2021. A total of 200,000 shares of common stock were initially reserved for issuance under this plan, which will automatically increase on January 1 of each year for a period of 10 years, beginning on January 1, 2021 and continuing through January 1, 2031, by the lesser of 1% of the total number of shares of common stock outstanding on the last day of the immediately preceding year; and 400,000 shares, except before the date of any such increase, the Board of Directors may determine that such increase will be less than the amount set forth above. As of December 31, 2021, no shares of common stock had been issued under the 2020 ESPP and 200,000 shares remained available for future issuance under the 2020 ESPP. On January 1, 2022, the shares reserved for issuance was increased to 387,812 shares. The first offering period has not yet been decided by the Company’s Board of Directors or designated committee of the Company’s Board of Directors.

Stock Option Activity

The following is a summary of the stock option award activity during the year ended December 31, 2021:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	1,247,158	$ 5.16	9.34	$ 1,486
Granted	1,231,965	7.59		
Exercised	(26,689)	(1.09)		
Forfeited	(146,055)	(5.76)		
Outstanding at December 31, 2021	2,306,379	$ 6.51	8.99	$ 983
Exercisable at December 31, 2021	503,206	$ 6.00	8.37	$ 544
Options expected to vest as of December 31, 2021	1,803,173	$ 6.83	9.16	$ 439

The weighted-average grant date fair value of options granted during the years ended December 31, 2021 and 2020 was $5.41 and $4.67, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the market price of the Company's common stock at the date of exercise. The aggregate intrinsic value of stock options exercised in the years ended December 31, 2021 and 2020 was $0.2 million and $0.1 million, respectively.

Stock-Based Compensation Expense

For the years ended December 31, 2021 and 2020, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	December 31, 2021	December 31, 2020
Volatility	85.67%-89.15%	83.3%-90.9%
Expected life (years)	5.49-6.68	4.25-9.34
Risk-free interest rate	0.66%-1.32%	0.3%-1.4%
Dividend rate	—%	—%

- Volatility—The Company estimates the expected volatility of its common stock at the date of grant based on the historical volatility of comparable public companies over the expected term.
- Expected life—The expected term represents the period that the Company's stock option grants are expected to be outstanding. The expected term of the options granted to employees and non-employee directors by the Company has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.
- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the statements of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	$ 1,014	$ 192
General and administrative	1,181	$ 165
Total stock-based compensation expense	$ 2,195	$ 357

No related tax benefits from stock-based compensation expense were recognized for the years ended December 31, 2021 and 2020. As of December 31, 2021, there was $8.3 million in unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 3.11 years.

9. LICENSE AGREEMENTS

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

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

In consideration of the license granted under the Emory License Agreement, the Company paid Emory University a nominal upfront payment. 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 The UAB Research Foundation, or 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 antidilution rights.

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

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

The term of the UABRF License Agreement will continue until the expiration of the licensed patents. The Company may terminate the UABRF License Agreement at will at any time upon prior written notice to UABRF. UABRF has the right to terminate the UABRF License Agreement if the Company materially breaches the agreement and fails to cure such breach within

a specified cure period, if the Company fails to diligently undertake development and commercialization activities as set forth in the development and commercialization plan, if the Company underreports its payment obligations or underpays by more than a specified threshold, if the Company challenges the validity or enforceability of any licensed patents, or if the Company becomes bankrupt or insolvent.

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. As of December 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 June 30, 2020, was determined to be immaterial based on the remote probability of an additional financing and the immaterial value of the total number of shares that could be issued pursuant to the provision. The antidilution provision was settled in August 2020 when the Company raised an additional $19.8 million in gross proceeds through the issuance and sale of Series A Preferred Stock for a total of $35.0 million in gross proceeds related to the issuance and sale of Series A Preferred Stock.

10. INCOME TAXES

For the years ended December 31, 2021 and 2020, the tax provision (benefit) consisted of (in thousands):

	December 31, 2021	December 31, 2020
Current provision (benefit):		
Federal	$ —	$ —
State	—	—
Total	—	—
Deferred provision (benefit)		
Federal	(2,670)	(1,569)
State	(1,938)	(1,116)
Total	(4,608)	(2,685)
Change in valuation allowance	4,608	2,685
Income tax provision (benefit)	$ —	$ —

The items accounting for the difference between income taxes computed at the federal statutory rate and the Company's effective tax rate for 2021 and 2020 were as follows:

	December 31, 2021	December 31, 2020
U.S Federal statutory rate	21%	21%
State taxes, net of federal benefit	10%	10%
Stock-based compensation	-2%	0%
Other permanent differences	-1%	0%
True up adjustments	3%	0%
Change in valuation allowance	-31%	-31%
Income tax provision (benefit)	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, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Stock-based compensation	$ 337	$ 155
Net operating loss carryforwards and alternative minimum tax credits	6,803	4,667
Lease liabilities	791	—
Reserves and accruals	304	—
Intangibles and fixed assets	1,922	—
Total deferred tax assets	10,157	4,822
Deferred tax liabilities:		
ROU assets	(766)	—
Property and equipment	—	(38)
Total deferred tax liabilities	(766)	(38)
Valuation allowance	(9,391)	(4,784)
Deferred tax assets (liabilities), net	$ —	$ —

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits 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 evaluated the impact of the CARES Act. At present, the Company does not expect that the NOL carryback provision or other provisions of the CARES Act resulting in a material tax benefit to the Company.

As of December 31, 2021, the Company had federal NOL carryforwards of approximately $20.1 million, New York State and City NOL carryforwards of approximately $30.1 million which will begin to expire in 2039. 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.

The Company has evaluated both positive and negative evidences and determined that negative evidence outweighed the positive evidence and that a full valuation allowance on its net deferred tax assets will be maintained. The net change in the valuation allowance for the year ended December 31, 2021 was an increase of $4.6 million.

IRC Section 382 imposes limitations on the use of net operating loss carryovers when the stock ownership of one or more 5% shareholders (shareholders owning 5% or more of the Company’s outstanding capital stock) has increased on a cumulative basis by more than 50 percentage points. Accordingly, there is a risk of an ownership change that could trigger a limitation of the use of the loss carryover. The Company has undertaken a formal IRC Section 382 study up until March 1, 2022. Management concluded that the Company did not undergo a no more than 50% ownership change defined under IRS Section 382(a); all the attributes disclosed in this footnotes reflect the conclusion of that study. However, subsequent ownership changes may further limit the Company's ability in the future to utilize its NOLs and other tax carryforwards.

In the ordinary course of business, the Company’s income tax returns are subject to examination by various taxing authorities. Such examinations may result in future tax and interest assessment by these taxing authorities. Accordingly, the Company believes that it is more likely than not that it will realize the benefits of tax positions it has taken in its tax returns or for the amount of any tax benefit that exceeds the cumulative probability threshold in accordance with FASB ASC 740. Differences between the estimated and actual amounts determined upon ultimate resolution, individually or in the aggregate, are not expected to have a material adverse effect on the Company’s financial position. The Company believes its tax positions are highly certain of being upheld upon examination. The Company is subject to the U.S. federal and state income taxes with varying statutes of limitations. Tax years from 2018 forward remaining open to examination due to the carryover of net operating losses or tax credits.

11. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Year Ended December 31,	
	2021	2020
Net loss	$ (14,653)	$ (8,557)
Cumulative dividends on convertible preferred stock	—	(1,783)
Net loss attributable to common stockholders	$ (14,653)	$ (10,340)
Net loss per share—basic and diluted	$ (1.47)	$ (3.02)
Weighted-average number of shares used in computing net loss per share—basic and diluted	9,969,733	3,419,075

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

	Year Ended December 31,	
	2021	2020
Convertible preferred stock	—	9,993,727
Stock options to purchase common stock	1,723,587	1,247,158

12. COMMITMENTS AND CONTINGENCIES

Intellectual Property

The Company has existing commitments to the licensors of the intellectual property which the Company has licensed. These commitments are based upon certain clinical research, regulatory, financial and sales milestones being achieved. Additionally, the Company is obligated to pay a single-digit royalty on commercial sales on a global basis. The royalty term is the later of 10 years from first commercial sale or expiration of the last-to-expire component of the licensed intellectual property.

Litigation Disclosure

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.

Legal Proceedings

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

13. FACILITY LEASES

The Company has historically entered into lease arrangements for its facilities. As of December 31, 2021, 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.

Finance Leases

The Company entered into an agreement with an equipment leasing company in 2018, which provided up to $1.4 million for equipment purchases in the form of sale and leasebacks or direct leases. As of December 31, 2021, the Company had completed the sale and leaseback for four pieces of equipment and is leasing three other items directly from the leasing company. The terms of the leases are three years and afterwards provide for either annual extensions or an outright purchase of the equipment.

The equipment leases require two advance rental payments to be held as security deposits. The security deposits held amounted to approximately $0.1 million as of December 31, 2021 and 2020, and are included in restricted cash on the balance sheets.

Operating Leases

In December 2020, the Company entered into an operating lease for office and laboratory space in Birmingham, Alabama, for a 63-month term, ending in February 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 September 2021, the Company entered into a new operating lease for office space in New York, New York, with a term commencing on September 15, 2021 and continuing through March 2027. 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 September 2021, the Company entered into a lease agreement with a third party to build out the Company's labs in Birmingham, Alabama. The agreement has a threshold of $4.0 million in total costs incurred. As of December 31, 2021, $0.2 million in expenses have been incurred and are classified as construction in progress on the balance sheet.

The operating leases required security deposits at the inception of each lease. The security deposits amounted to approximately $17,000 and $251,000 as of December 31, 2021, which are included in other non-current assets and restricted cash on the balance sheet, respectively.

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 year ended December 31, 2021 (in thousands):

	Year Ended December 31,
Lease Cost	
Amortization of finance right-of-use assets	$ 537
Interest on finance lease liabilities	86
Operating lease cost	280
Short-term lease cost	460
Total lease cost	$ 1,363

	December 31, 2021
Other Operating Lease Information	
Cash paid for amounts included in the measurement of lease liability – finance leases	$ 86
Cash paid for amounts included in the measurement of lease liability – operating leases	$ 158
Weighted-average remaining lease term – finance leases	1.64
Weighted-average remaining lease term – operating leases	4.73
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 December 31, 2021 (in thousands):

	Financing Leases	Operating Leases
2022	$ 435	$ 405
2023	252	478
2024	30	490
2025	—	502
2026	—	311
Thereafter	—	45
Total lease payment	717	2,231
Less: interest	56	482
Total lease liabilities	661	1,749
Less: short-term lease liability	392	234
Long-term lease liability	$ 269	$ 1,515

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting.

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Attestation Report of the Registered Public Accounting Firm.

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Proposal 1: Election of Directors,” “Information About Our Executive Officers,” “Information Regarding the Board and Corporate Governance” and “Delinquent Section 16(a) Reports,” if applicable, in our 2022 Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Officer and Director Compensation” in our 2022 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” in our 2022 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Transactions with Related Persons” and “Information Regarding the Board and Corporate Governance – Board Independence” in our 2022 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Independent Registered Public Accounting Firm Fees” in our 2022 Proxy Statement.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

The financial statements schedules and exhibits filed as part of this Annual Report are as follows:

(a)(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(a)(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(a)(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on August 3, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on August 3, 2021).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-249530), filed with the SEC on November 5, 2020).
4.2	Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated May 7, 2018 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-249530), filed with the SEC on October 16, 2020).
4.3	Description of the Registrant's Securities.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on November 5, 2020).
10.2+	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.3+	Forms of Option Grant Notice and Option Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.4+	2020 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (File No. 333-259458), filed with the SEC on September 10, 2021).
10.5+	Forms of Option Grant Notice and Option Agreement under 2020 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on November 5, 2020).
10.6+	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under 2020 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on November 5, 2020).
10.7+	2020 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (File No. 333-259458), filed with the SEC on September 10, 2021).
10.8+	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on November 5, 2020).
10.9†	Exclusive License Agreement, dated March 10, 2016, between the Registrant and The UAB Research Foundation, as amended (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.10†	First Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.11†	Second Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.12†	Third Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.13†	Fourth Amendment to Exclusive License Agreement, dated December 14, 2016, between the UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.14†	Exclusive License Agreement, dated June 10, 2016, between Emory University, Children's Healthcare of Atlanta, Inc., and UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.15†	First Amendment to Exclusive License Agreement between Emory University, Children's Healthcare of Atlanta, Inc., The UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).

10.16†	Second Amendment to Exclusive License Agreement between Emory University, Children's Healthcare of Atlanta, Inc., The UAB Research Foundation and the Registrant (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-249530), filed with the Commission on October 16, 2020).
10.17+	Amended and Restated Employment Agreement, between Registrant and William Ho, dated December 1, 2020 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on July 22, 2021).
10.18+	Amended and Restated Employment Agreement between Registrant and Lawrence Lamb, dated December 31, 2020 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A (File No. 333-249530), filed with the Commission on July 22, 2021).
10.19+	Employment Agreement between Registrant and Trishna Goswami, dated October 7, 2021.
10.20+	Employment Agreement between Registrant and Patrick McCall, dated January 20, 2021.
23.1	Consent of Independent Registered Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

+ Indicates a management contract or compensatory plan.

† Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the Securities and Exchange Commission, certain portions of this exhibit have been redacted. The Registrant hereby agrees to furnish supplementally to the Securities and Exchange Commission, upon its request, an unredacted copy of this exhibit

Item 16. Form 10-K Summary

None.

SIGNATURES

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

IN8bio, Inc.

March 17, 2022 By: /s/ William Ho
William Ho
Chief Executive Officer
(Principal Executive Officer)

March 17, 2022 By: /s/ Patrick McCall
Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints William Ho and Patrick McCall, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report on Form 10-K, and to file the same, with all 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, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ William Ho **William Ho**	Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2022
/s/ Patrick McCall **Patrick McCall**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 17, 2022
/s/ Alan S. Roemer **Alan S. Roemer**	Chairman of the Board of Directors	March 17, 2022
/s/ Peter Brandt **Peter Brandt**	Director	March 17, 2022
/s/ Emily Fairbairn **Emily Fairbairn**	Director	March 17, 2022
/s/ Luba Greenwood **Luba Greenwood**	Director	March 17, 2022
/s/ Travis Whitfill **Travis Whitfill**	Director	March 17, 2022

EXHIBIT 4.3

DESCRIPTION OF THE REGISTRANTS' SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description summarizes selected information regarding our capital stock, as well as provisions of; (i) our amended and restated certificate of incorporation; (ii) our amended and restated bylaws; and (iii) the general Corporation Law of the State of Delaware, or the DGCL. The following summary is qualified in its entirety by, and should be read in conjunction with, the amended and restated certificate of incorporation and the amended and restated bylaws, copies of which have been filed as exhibits to our Annual Report on Form 10-K to which this exhibit is attached, and the applicable provisions of the DGCL.

General

Our authorized capital stock consists 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

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, is 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

Under the amended and restated certificate of incorporation, our board of directors 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.

Registration Rights

We are party to an investors' rights agreement that provides that certain holders of certain shares of our common stock have registration rights, as set forth below. The investors' rights agreement was entered into as of May 7, 2018. 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 of 1933, as amended (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

Certain holders of registerable securities 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

Certain holders of registerable securities are entitled to rights to notice in an offering and to include their shares of registrable securities in an offering. In the event that we propose to register any of our

securities under the Securities Act, 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

Certain holders of shares of common stock are 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:

- 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 is 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 2⁄3% of the voting power of all of our then-outstanding 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 2⁄3% 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 2⁄3% 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 provides 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 jurisdiction 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 provides 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.

EXHIBIT 10.19

EMPLOYMENT AGREEMENT

This Employment Agreement (the "***Agreement***") is entered into as of October 7, 2021 (the "***Effective Date***"), by and between Trishna Goswami, MD (the "***Executive***") and IN8bio, Inc., its subsidiaries, parents, affiliates, predecessors, successors and assigns (together, the "***Company***") (Executive and the Company together, the "***Parties***").

RECITALS

WHEREAS, the Company wishes to employ Executive and Executive wishes to be employed by the Company;

WHEREAS, the Company and Executive desire to enter into this Agreement to establish and govern the terms and conditions of Executive's employment by the Company.

NOW THEREFORE, in consideration of the promises and mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties; Location. Subject to the terms and conditions of this Agreement, Executive shall hold the position of Chief Medical Officer. Executive's activities shall be as directed by the Company's Chief Executive Officer (the "**CEO**") and shall include such duties and activities as typically associated with Executive's position, and as otherwise may be assigned to Executive from time to time. Without limiting Executive's rights under Section 5.3 below, the Company reserves the right to change or modify Executive's title and/or duties as business needs may require. Executive shall devote Executive's business energies, interest, abilities and productive time to the proper and efficient performance of Executive's duties under this Agreement. Executive initially shall report to the CEO and work from the Company's offices/facilities in New York City when necessary. Otherwise, Executive is permitted to work from any location within 100 miles of New York City and further provided that the Company reserves the right to require business travel.

1.2 Policies and Procedures. The employment relationship between the parties shall be governed by this Agreement and by the policies and practices established by the Company's Board of Diretors (the "***Board***"). In the event that the terms of this Agreement differ from or are in conflict with the Company's policies or practices, this Agreement shall control.

1.3 Exclusive Employment; Agreement not to Participate in Company's Competitors. Except with the prior written consent of the Board, Executive will not, during the period of employment by the Company, undertake or engage in any other employment, or directly or indirectly, undertake or engage in any employment, directorships, occupation, or business activity that competes with directly or indirectly, or is known by Executive to be adverse or antagonistic to the business, prospective business, or financial or other interests of the Company, provided, however, that the Company agrees that Executive may continue to serve in any roles, positions, and/or appointments listed in Exhibit A to this Agreement, or any similar roles, positions, and/or appointments mutually agreed upon by the Company and the Executive, provided, in each case, they do not interfere with Executive's job duties for the Company

1.4 Start Date. Executive's employment with the Company shall commence on November 15, 2021.

2. At-Will Employment. Executive's employment relationship with the Company is, and shall at all times be, at-will. This means that either Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without cause or advance notice.

3. Compensation and Benefits.

3.1 Salary. Beginning on the Effective Date, Executive shall earn an initial base salary of $450,000 per annum, less payroll deductions and all required withholdings (the "***Base Salary***"). The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary may be adjusted from time to time in the Company's discretion.

3.2 Sign-On Bonus. Within thirty (30) days after the Start Date, the Company will pay Executive a one-time start bonus of $10,000, less payroll deductions and all required withholdings. The net amount of this bonus must be repaid to the Company by Executive if Executive resigns from employment with the Company without Good Reason within one (1) year after the Start Date.

3.3 Performance Bonus. Each full calendar year, Executive will be eligible to earn a cash bonus of up to 40% of Executive's Base Salary based on the Board's assessment of Executive's individual performance and overall Company performance (the "***Annual Bonus***"). In order to earn and receive the bonus, Executive must remain employed by the Company through and including the bonus payout date, which will be on or before March 15th of the year following the year to which it relates. The determination of whether Executive has earned a bonus and the amount thereof shall be determined by the Board (and/or a committee thereof) in its sole and absolute discretion in good faith. The Company reserves the right to create or modify the bonus criteria and targets from year to year.

3.4 Stock Options. Subject to approval by our Board of Directors or designated committee, IN8bio will provide to you a new hire equity award of stock options representing the right to purchase shares of Company common stock (the "***Option***"). Your new hire stock option award will be 250,000 stock options with an exercise or strike price equal to the closing sales price as quoted on the Nasdaq Stock Market as of the date of the grant by the Board. The anticipated Option grant will be governed by the terms and conditions of the Company's 2021 Equity Incentive Plan and your grant agreement will include time-based vesting, as described below. No right to any stock or option is earned or accrued until such time that vesting occurs, nor does this grant confer any right to continued vesting or employment. The terms of this Option grant are as follows: one-fourth (1/4th) of the shares vest on the one year anniversary of the vesting commencement date, and none before such date; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the

day after the first anniversary of the vesting commencement date, subject to your continuous service as of each such date. You will be eligible to receive awards of stock options, restricted stock or other equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or a committee of the Board shall determine in its discretion whether Executive shall be granted any such equity awards and the terms of any such award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

3.5 Standard Company Benefits. Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company employees including, but not limited to, to the extent offered, customary health, life insurance, 401(k)/defined benefit, and disability plans. The Company reserves the right to modify, add or eliminate benefits from time to time. Executive will also be eligible to accrue and use paid time off ("***PTO***") in accordance with the Company's PTO policy.

3.6 Expense Reimbursements. The Company will reimburse Executive for all reasonable business expenses Executive incurs in conducting Executive's duties hereunder, pursuant to the Company's usual expense reimbursement practices.

4. Proprietary Information Obligations. In connection with Executive's employment with the Company, Executive will receive and have access to Company confidential information and trade secrets. Accordingly, Executive acknowledges and agrees that Executive will review the enclosed Employee Confidential Information and Inventions Assignment Agreement and execute it on even date herewith (the "***CIIAA***").

5. Termination of Employment; Severance.

5.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

5.2 Executive's Resignation without Good Reason.

(a) Executive may resign from employment with Company without Good Reason.

(b) If Executive resigns from employment with the Company without Good Reason (as defined below), then, provided that Executive provides at least thirty (30) days prior written notice (or such shorter prior written notice period agreed to in writing tby the Company), the Company shall pay Executive any earned but unpaid base salary accrued through the date of termination, reimbursement for any unreimbursed business expenses incurred through the termination date with proper submission of related receipts and/or invoices and all accrued but unused paid time off, at the rates then in effect, less standard deductions and withholdings. Executive will no longer vest in any equity interests (though any vested equity remains the property of the Executive, as permitted by and subject to the relevant stock agreement(s) and plan(s)) and the Company shall thereafter have no further obligations to Executive, except as may otherwise be required by law.

5.3 Termination Without Cause; Resignation for Good Reason.

(a) The Company may terminate Executive's employment with the Company at any time without Cause (as defined below). Further, Executive may resign at any time for Good Reason (as defined below).

(b) In the event Executive's employment with the Company is terminated by the Company without Cause, or Executive resigns for Good Reason, then provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), and provided that Executive remains in compliance with the terms of this Agreement, subject to Section 5.7, Executive shall receive the following:

(i) The Company shall pay Executive any earned but unpaid base salary accrued through the date of termination and all accrued but unused PTO, at the rates then in effect, less standard deductions and withholdings.

(ii) The Company shall pay Executive, as severance, twelve (12) months of Executive's Base Salary in effect as of the date of Executive's employment termination, subject to standard payroll deductions and withholdings (the "***Severance***"). The Severance will be paid in equal installments on the Company's regular payroll schedule over the twelve (12) month period following Executive's Separation from Service; *provided, however,* that no payments will be made prior to the 60th day following Executive's Separation from Service. On the 60th day following Executive's Separation from Service, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled.

(iii) To the extent the Executive has actually achieved any of the performance goals set by the Board for such calendar year, the Company shall pay Executive a prorated Annual Bonus (calculated as the Annual Bonus that would have been paid for the entire calendar year multiplied by a fraction, the numerator of which is equal to the number of days Executive worked in the applicable calendar year, and the denominator of which is equal to the total number of days in such year).

(iv) Provided Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) ("***COBRA Premiums***") through the period (the "***COBRA Premium Period***") starting on Executive's Separation from Service and ending on the earliest to occur of: (i) nine (9) months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the "***Special Cash Payment***"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

5.4 Termination for Cause, Death, or Disability.

(a) The Company may terminate Executive's employment with the Company at any time for Cause. Executive's employment with the Company may also be terminated due to Executive's death or disability.

(b) If the Company terminates Executive's employment for Cause, or upon Executive's death or disability, then Executive will no longer vest in any equity interests (though any vested equity remains the property of the Executive, as permitted by and subject to the relevant stock agreement(s) and plan(s)) and all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned). The Company shall thereafter have no further obligations to Executive, except as may otherwise be required by law.

5.5 Effect of Termination. Executive agrees that should Executive's employment be terminated for any reason, Executive shall be deemed to have resigned from any and all positions, including any director and/or officer positions with the Company and its affiliated entities.

5.6 Section 409A Compliance. It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Severance benefits shall not commence until the Executive has a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "separation from service"). Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of termination to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i), and if any of the payments set forth herein are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six-month period measured from the date of termination, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. Finally, if the period during which Executive may consider and sign a release in connection with the receipt of severance benefits spans two calendar years, the payment of severance will not be made or begin until the later calendar year.

5.7 Release. As a condition precedent to receipt of the benefits set forth in Section 5.3 above or Section 6 below, Executive shall furnish to the Company an executed waiver and release of claims in a form to be provided by the Company, which shall include confidentiality, non-disclosure, and non-disparagement provisions (the ***"Release"***) within the time period specified therein, but in no event later than forty-five (45) days following Executive's termination. The Release may also include an obligation for Executive to provide reasonable transition assistance and consulting services to the Company on an as-needed basis through the first three (3) months following the Executive's employment termination date with any additional services beyond three months to be paid at $200 per hour. During any transition period immediately commencing after employment terminates, the Company shall reimburse Executive for reasonable and necessary business expenses, and she shall remain covered under the then-current D&O policy. Executive acknowledges and agrees that such transition services shall be fully compensated by the benefits described herein.

6. Benefits in Connection with Change of Control

6.1 Termination of Employment in Connection with a Change of Control. If there is a Change of Control (as defined below) and (i) Executive's employment is terminated Without Cause (as defined below), or (ii) Executive terminates his/her employment with Good Reason (as defined below), in either case within three (3) months prior to, or twelve (12) months following the effective date of the Change of Control, and provided a Release (as discussed in Section 5.7) has become effective, then, in substitution for any benefits provided in Section 5.3, Executive shall be entitled to the following benefits: (A) a lump sum payment equal to the sum of (y) twelve (12) months of Executive's then-current annual Base Salary and (z) 100% of the current target Annual Bonus, to be made not later than 60 days following Executive's date of termination; and (B) the amount of any COBRA continuation premium payments made by Executive during the twelve (12) month period following the date of termination, or the period ending when Executive becomes eligible for comparable group medical benefits from another source (whichever comes first). For avoidance of doubt, under no circumstances shall Executive receive benefits under both this Section 6.1 and Section 5.3.

6.2 Acceleration of Options; Change of Control. If the Company terminates Executive's employment with the Company without Cause, or Executive resigns for Good Reason, in either case within three (3) months prior to, or twelve (12) months following the closing of a Change of Control (as defined below), then in addition to the benefits set forth in Section 6.1 and pursuant to the terms of Section 5.7, the Company will fully accelerate the vesting of any equity interests granted to Executive, such that 100% of the then-unvested shares subject to such equity interests will be deemed vested and exercisable as of Executive's last day of employment.

7. Definitions

7.1 Cause. For purposes of this Agreement, "**Cause**" shall mean the occurrence of any of the following: (i) Executive's conviction of any felony or any crime involving fraud or dishonesty; (ii) Executive's participation in fraud, willful act of dishonesty or act of gross misconduct against the Company and/or its Board that results in material financial or reputational harm to the Company; (iii) Executive's material violation of any statutory or fiduciary duty, or duty of loyalty, owed to the Company that is not sufficiently remedied within thirty days after written notice from the Company; or (iv) Executive's material violation of material Company policy that is not sufficiently remedied within thirty days after written notice from the Company. Prior to a termination for Cause pursuant to (iv) above, to the extent such event(s) is capable of being cured by Executive and to the extent it is the first such instance giving rise to the notice described herein, (A) the Company shall give the Executive a single notice of such event(s), which notice shall specify in reasonable detail the circumstances constituting Cause, (B) Executive shall have thirty (30) days after the delivery of such notice to cure the event(s) giving rise to Cause, the existence of such cure to be determined by the Board in good faith, provided that the Company reserves the right put Executive on a paid leave of absence during such period and limit or terminate Executive's access to Company systems and property so long as such measures do not substantially interfere with Executive's ability to cure the Cause of her termination during the cure period.

7.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (a) a material reduction in Executive's base salary, which the parties agree is a reduction of at least 10% of Executive's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); or (b) a material reduction in Executive's title or duties (including responsibilities and/or authorities) including, but not limited to, Executive being required to report to someone other than the CEO and/or President (or division head, if Company is acquired and

operates as a division of the acquiror), *provided, however,* that a change in job position shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties; (c) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than sixty (60) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; (d) a material breach by the Company of this Agreement or any equity award agreement that is not sufficiently remedied within thirty days after written notice from the Company. In order to resign for Good Reason, Executive must provide written notice to the Company's CEO within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than 90 days after the expiration of the cure period.

7.3 Change of Control. For purposes of this Agreement, **"Change of Control"** is defined in the Company's 2021 Equity Incentive Plan.

8. Parachute Payments. If any payment or benefit Executive would receive from the Company or otherwise in connection with a Change of Control or other similar transaction (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

The determinations made pursuant to this Section 8, and the assumptions to be utilized in arriving at such determinations, shall be made by a nationally recognized accounting or consulting firm chosen by the Board or a committee thereof (the "280G Calculation Firm") at the expense of the Company. The 280G Calculation Firm shall take into account whether, and to what extent (if any), such Payments or portions thereof may properly be treated as "reasonable compensation for personal services rendered" by the Executive before, or after, the 280G Change in Control, within the meaning of Code section 280G(b)(4) and the regulations issued thereunder, as well as any other appropriate provisions of Section 280G of the Code and the regulations thereunder

that may cause such Payments to appropriately be characterized as other than "parachute payments." The 280G Calculation Firm shall provide a written report of its determinations hereunder, including detailed supporting calculations, both to the Executive and to the Company.

8.1 If Executive receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

9. ARBITRATION. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, the CIIAA, or Executive's employment, or the termination of Executive's employment, including but not limited to all statutory claims, with the exception of discrimination and harassment claims, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16 (the "***FAA***"), and to the fullest extent permitted by law, by final, binding and confidential arbitration by a single arbitrator conducted in New York, New York by Judicial Arbitration and Mediation Services Inc. ("***JAMS***") under the then applicable JAMS rules (at the following web address: https://www.jamsadr.com/rules-employment-arbitration/); provided, however, this arbitration provision shall not apply to sexual harassment and discrimination claims to the extent prohibited by applicable law that is not preempted by the FAA. A hard copy of the rules will be provided to Executive upon request. A hard copy of the rules will be provided to Executive upon request. **By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this Agreement) shall be decided by a federal court in the State of New York. However, procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. Executive and the Company shall equally share all JAMS' arbitration fees. To the extent JAMS does not collect or Executive otherwise does not pay to JAMS an equal share of all JAMS' arbitration fees for any reason, and the Company pays JAMS Executive's share, Executive acknowledges and agrees that the Company shall be entitled to recover from Executive half of the JAMS arbitration fees invoiced to the parties (less any amounts Executive paid to JAMS) in a federal or state court of competent jurisdiction. Except as modified in the CIIAA, each party is responsible for its own attorneys' fees. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent

irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. To the extent applicable law prohibits mandatory arbitration of sexual harassment or discrimination claims and is not preempted by the FAA, in the event Executive intends to bring multiple claims, including a sexual harassment or discrimination claim, the sexual harassment and/or discrimination claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

10. GENERAL PROVISIONS.

10.1 Representations and Warranties. Executive represents and warrants that Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity.

10.2 Advertising Waiver. Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company in which Executive's name and/or pictures of Executive appear. Executive hereby waives and releases any claim or right Executive may otherwise have arising out of such use, publication or distribution.

10.3 D&O Insurance. Executive shall be entitled to indemnification from the Company pursuant to, and in accordance with the terms of, (i) the Company's charter and bylaws, to the extent that indemnification of Executive is provided for therein, and (ii) any D&O insurance policy covering Executive purchased by the Company. The D&O insurance policy (or policies) shall be kept in place at the Company's expense, during the term of this Agreement and thereafter until at least the second anniversary of the date Executive's employment with the Company terminates, providing coverage to Executive that is no less favorable to her in any respect than the coverage then being provided to any other current or former director or officer of the Company

10.4 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

10.5 Miscellaneous. This Agreement, along with the CIIAA, constitutes the complete, final and exclusive embodiment of the entire agreement between Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both Executive and a duly authorized member of the Board. This Agreement will bind the heirs, personal representatives, successors and assigns of both Executive and the Company, and inure to the benefit of both Executive and the Company, and to her and its heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New York. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this

Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

IN8BIO, INC.

By: _____
Name: William Ho
Title: President & CEO

Accepted and agreed:

/s/ Trishna Goswami, MD

_____
TRISHNA GOSWAMI, MD

Exhibit A

Permitted Non-Company Positions

EXHIBIT 10.20

EMPLOYMENT AGREEMENT

This Employment Agreement (the "***Agreement***") is entered into as of January 20, 2021 (the "***Effective Date***"), by and between Patrick McCall (the "***Executive***") and IN8bio, Inc., its subsidiaries, parents, affiliates, predecessors, successors and assigns (together, the "***Company***") (Executive and the Company together, the "***Parties***").

RECITALS

WHEREAS, the Company wishes to employ Executive and Executive wishes to be employed by the Company;

WHEREAS, the Company and Executive desire to enter into this Agreement to establish and govern the terms and conditions of Executive's employment by the Company.

NOW THEREFORE, in consideration of the promises and mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties; Location. Subject to the terms and conditions of this Agreement, Executive shall hold the position of Chief Financial Officer. Executive's activities shall be as directed by the Company's Chief Executive Officer (the "**CEO**") and shall include such duties and activities as typically associated with Executive's position, and as otherwise may be assigned to Executive from time to time. The Company reserves the right to change or modify Executive's title and/or duties as business needs may require. Executive shall devote Executive's business energies, interest, abilities and productive time to the proper and efficient performance of Executive's duties under this Agreement. Executive initially shall report to the CEO and work primarily from the Company's offices/facilities in New York City provided that the Company reserves the right to require business travel.

1.2 Policies and Procedures. The employment relationship between the parties shall be governed by this Agreement and by the policies and practices established by the Company's Board of Directors (the "***Board***"). In the event that the terms of this Agreement differ from or are in conflict with the Company's policies or practices, this Agreement shall control.

1.3 Exclusive Employment; Agreement not to Participate in Company's Competitors. Except with the prior written consent of the Board, Executive will not, during the period of employment by the Company, undertake or engage in any other employment, or directly or indirectly, undertake or engage in any employment, directorships, occupation, or business activity that competes with directly or indirectly, or is known

by Executive to be adverse or antagonistic to the business, prospective business, or financial or other interests of the Company, provided, however, that the Company agrees that Executive may continue to serve in any roles, positions, and/or appointments listed in Exhibit A to this Agreement, or any similar roles, positions, and/or appointments mutually agreed upon by the Company and the Executive, provided, in each case, they do not interfere with Executive's job duties for the Company.

1.4 Start Date. Executive's employment with the Company shall commence as mutually agreed upon by the parties (the "Start Date") but in no event later than February 8, 2021.

2. At-Will Employment. Executive's employment relationship with the Company is, and shall at all times be, at-will. This means that either Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without cause or advance notice.

3. Compensation and Benefits.

3.1 Salary. Beginning on the Effective Date, Executive shall earn an initial base salary of $370,000 per annum, less payroll deductions and all required withholdings (the "***Base Salary***"). The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary may be adjusted from time to time in the Company's discretion.

3.2 Sign-On Bonus. Within thirty (30) days after the Start Date, the Company will pay Executive a one-time start bonus of $50,000, less payroll deductions and all required withholdings. The net amount of this bonus must be repaid to the Company by Executive if Executive resigns from employment with the Company without Good Reason within one (1) year after the Start Date.

3.3 Performance Bonus. Each full calendar year, Executive will be eligible to earn a cash bonus of up to 40% of Executive's Base Salary, less payroll deductions and all required withholdings, based on the Board's assessment of Executive's individual performance and overall Company performance (the "***Annual Bonus***"). In order to earn and receive the bonus, Executive must remain employed by the Company through and including the bonus payout date, which will be on or before March 15th of the year following the year to which it relates. The determination of whether Executive has earned a bonus and the amount thereof shall be determined by the Board (and/or a committee thereof) in its sole and absolute discretion. The Company reserves the right to modify the bonus criteria and targets from year to year.

3.4 Stock Options. Subject to approval by our Board of Directors, on or within 7 business days following the Start Date, IN8bio will provide to you a new hire equity award of stock options representing the right to purchase shares of Company common stock (the "Option"). Your new hire stock option award will be 188,816 stock options with a strike price at the then approved 409A valuation price. The anticipated Option grant will be governed by the terms and conditions of the Company's 2018 Equity Incentive Plan (including its net exercise provision) and your grant agreement will include time-based vesting, as described below. No right to any stock or option is earned or accrued until such time that vesting occurs, nor does this grant confer any right to continued vesting or employment. The terms of this Option grant are as follows: one-fourth (1/4th) of the shares vest one year and a day after the vesting commencement date, and none before such date; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the day after the first anniversary of the vesting commencement date, subject to your continuous service as of each such date. You will be eligible to receive awards of stock options, restricted stock or other equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or a committee of the Board shall determine in its discretion whether Executive shall be granted any such equity awards and the terms of any such award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time. There is no Company repurchase right of vested Option shares or right of first refusal with respect to vested Option shares after a Company IPO.

3.5 Standard Company Benefits. Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company employees. The Company reserves the right to modify, add or eliminate benefits from time to time. Executive will also be eligible to accrue and use paid time off ("***PTO***") in accordance with the Company's PTO policy.

3.6 Expense Reimbursements. The Company will reimburse Executive for all reasonable business expenses Executive incurs in conducting Executive's duties hereunder, pursuant to the Company's usual expense reimbursement practices.

4. Proprietary Information Obligations. In connection with Executive's employment with the Company, Executive will receive and have access to Company confidential information and trade secrets. Accordingly, Executive acknowledges and agrees that Executive will review the enclosed Employee Confidential Information and Inventions Assignment Agreement and execute it on even date herewith (the "***CIIAA***").

5. Termination of Employment; Severance.

5.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

5.2 Executive's Resignation without Good Reason.

(a) Executive may resign from employment with Company without Good Reason.

(b) If Executive resigns from employment with the Company without Good Reason (as defined below), then, provided that Executive provides at least thirty (30) days prior written notice (or such shorter prior written notice period agreed to in writing by the Company), the Company shall pay Executive any earned but unpaid base salary accrued through the date of termination and all accrued but unused paid time off, at the rates then in effect, less standard deductions and withholdings. Executive will no longer vest in any equity interests and the Company shall thereafter have no further obligations to Executive, except as may otherwise be required by law.

5.3 Termination Without Cause; Resignation for Good Reason.

(a) The Company may terminate Executive's employment with the Company at any time without Cause (as defined below). Further, Executive may resign at any time for Good Reason (as defined below).

(b) In the event Executive's employment with the Company is terminated by the Company without Cause, or Executive resigns for Good Reason, then provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), and provided that Executive remains in compliance with the terms of this Agreement, subject to Section 5.7, Executive shall receive the following:

(i) The Company shall pay Executive any earned but unpaid base salary accrued through the date of termination and all accrued but unused PTO, at the rates then in effect, less standard deductions and withholdings.

(ii) The Company shall pay Executive, as severance, twelve (12) months of Executive's Base Salary in effect as of the date of Executive's employment termination, subject to standard payroll deductions and withholdings (the "***Severance***"). The Severance will be paid in equal installments on the

Company's regular payroll schedule over the twelve (12) month period following Executive's Separation from Service; *provided, however,* that no payments will be made prior to the 60th day following Executive's Separation from Service. On the 60th day following Executive's Separation from Service, the Company will pay Executive in a lump sum the Severance that Executive would have received on or prior to such date under the standard payroll schedule but for the delay while waiting for the 60th day in compliance with Code Section 409A, with the balance of the Severance being paid as originally scheduled.

(iii) To the extent the Executive has actually achieved any of the performance goals set by the Board for such calendar year, the Company shall pay Executive a prorated Annual Bonus (calculated as the Annual Bonus that would have been paid for the entire calendar year multiplied by a fraction, the numerator of which is equal to the number of days Executive worked in the applicable calendar year, and the denominator of which is equal to the total number of days in such year).

(iv) Provided Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) ("***COBRA Premiums***") through the period (the "***COBRA Premium Period***") starting on Executive's Separation from Service and ending on the earliest to occur of: (i) twelve (12) months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the "***Special Cash Payment***"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

5.4 Termination for Cause, Death, or Disability.

(a) The Company may terminate Executive's employment with the Company at any time for Cause. Executive's employment with the Company may also be terminated due to Executive's death or disability.

(b) If the Company terminates Executive's employment for Cause, or upon Executive's death or disability, then Executive will no longer vest in any equity interests and all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned). The Company shall thereafter have no further obligations to Executive, except as may otherwise be required by law. Notwithstanding the above, to the extent that the Company's performance goals set by the Board for such calendar year in which Executive's employment terminates have been satisfied, the Company shall pay Executive a prorated Annual Bonus (calculated as the Annual Bonus that would have been paid for the entire calendar year multiplied by a fraction, the numerator of which is equal to the number of days Executive worked in the applicable calendar year, and the denominator of which is equal to the total number of days in such year), which shall be payable at the time that bonuses are paid to other executives of the Company.

5.5 Effect of Termination. Executive agrees that should Executive's employment be terminated for any reason, Executive shall be deemed to have resigned from any and all positions, including any director and/or officer positions with the Company and its affiliated entities.

5.6 Section 409A Compliance. It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Severance benefits shall not commence until the Executive has a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "separation from service"). Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of termination to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i), and if any of the payments set forth herein are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six-month period measured from the date of termination, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred. Finally, if the period during which Executive may consider and sign a release in connection with the receipt of severance benefits spans two calendar years, the payment of severance will not be made or begin until the later calendar year.

5.7 Release. As a condition precedent to receipt of the benefits set forth in Section 5.3 above or Section 6 below, Executive shall furnish to the Company an executed waiver and release of claims in a form to be provided by the Company, which shall include confidentiality, non-disclosure, and non-disparagement provisions, and may include an obligation for Executive to provide reasonable transition assistance and consulting services to the Company on an as-needed basis through no later than the first anniversary of Executive's employment termination date (the ***"Release"***) within the time period specified therein, but in no event later than forty-five (45) days following Executive's termination. Executive acknowledges and agrees that such transition services shall be fully compensated by the benefits described herein.

6. Benefits in Connection with Change of Control

6.1 Termination of Employment in Connection with a Change of Control. If there is a Change of Control (as defined below) and (i) Executive's employment is terminated Without Cause (as defined below), or (ii) Executive terminates his/her employment with Good Reason (as defined below), in either case within three (3) months prior to, or twelve (12) months following the effective date of the Change of Control, and provided a Release (as discussed in Section 5.7) has become effective, then, in substitution for any benefits provided in Section 5.3, Executive shall be entitled to the following benefits: (A) a lump sum payment equal to the sum of (y) twelve (12) months of Executive's then-current annual Base Salary and (z) 100% of the current target Annual Bonus, to be made not later than 60 days following Executive's date of termination; and (B) the amount of any COBRA continuation premium payments made by Executive during the twelve (12) month period following the date of termination, or the period ending when Executive becomes eligible for comparable group medical benefits from another source (whichever comes first). For avoidance of doubt, under no circumstances shall Executive receive benefits under both this Section 6.1 and Section 5.3.

6.2 Acceleration of Options; Change of Control. If the Company terminates Executive's

employment with the Company without Cause, or Executive resigns for Good Reason, in either case within three (3) months prior to, or twelve (12) months following the closing of a Change of Control (as defined below), then in addition to the benefits set forth in Section 6.1 and pursuant to the terms of Section 5.7, the Company will fully accelerate the vesting of any equity interests granted to Executive, such that 100% of the then-unvested shares subject to such equity interests will be deemed vested and exercisable as of Executive's last day of employment.

7. DEFINITIONS

7.1 Cause. For purposes of this Agreement, "**Cause**" shall mean the occurrence of any of the following: (i) Executive's conviction of any felony or any crime involving fraud or dishonesty; (ii) Executive's participation in fraud, act of dishonesty or act of gross misconduct against the Company and/or its Board that results in material financial or reputational harm to the Company; (iii) Executive's material violation of any statutory or fiduciary duty, or duty of loyalty, owed to the Company; or (iv) Executive's material violation of material Company policy. Prior to a termination for Cause pursuant to (iv) above, to the extent such event(s) is capable of being cured by Executive and to the extent it is the first such instance giving rise to the notice described herein, (A) the Company shall give the Executive a single notice of such event(s), which notice shall specify in reasonable detail the circumstances constituting Cause, (B) Executive shall have thirty (30) days after the delivery of such notice to cure the event(s) giving rise to Cause, the existence of such cure to be determined by the Board in good faith, provided that the Company reserves the right put Executive on a paid leave of absence during such period and terminate Executive's access to Company systems and property so long as such measures do not substantially interfere with Executive's ability to cure the Cause of his termination during the cure period.

7.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (a) a material reduction in Executive's base salary, which the parties agree is a reduction of at least 10% of Executive's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); or (b) a material reduction in Executive's duties (including responsibilities and/or authorities), *provided, however,* that a change in job position shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties; or (c) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than sixty (60) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation. In order to resign for Good Reason, Executive must provide written notice to the Company's CEO within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than 90 days after the expiration of the cure period.

7.3 Change of Control. For purposes of this Agreement, **"Change of Control"** is defined in the Company's 2018 Equity Incentive Plan.

8. Parachute Payments. If any payment or benefit Executive would receive from the Company or otherwise in connection with a Change of Control or other similar transaction (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and

local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

8.1 If Executive receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

8.2 Notwithstanding anything to the contrary in this Section 8, to the extent that Executive agrees, in accordance with Section 280G of the Code, to waive his rights to receive or retain all the payments or benefits from the Company or its subsidiaries contingent on a change in ownership or control of the Company in excess of $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code and none of the Company's stock is readily tradeable on an established securities market or otherwise immediately prior to such change in ownership or control, the Company shall use commercially reasonable efforts to obtain shareholder approval as may be required by the terms of Section 280G(b)(5)(B) of the Code so as to render the parachute payment provisions of Section 280G of the Code inapplicable to any and all accelerated vesting payments, benefits, options and/or shares provided pursuant to agreements, contracts or arrangements covering Executive that might otherwise result, separately or in the aggregate, in the payment of any amount and/or the provision of any benefit that would not be deductible by reason of Section 280G of the Code, with such shareholder vote to be obtained in a manner which satisfies all applicable requirements of Section 280G(b)(5)(B) of the Code and the regulations promulgated thereunder.

9. Arbitration. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, the CIIAA, or Executive's employment, or the termination of Executive's employment, including but not limited to all statutory claims, with the exception of discrimination and harassment claims, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16 (the "***FAA***"), and to the fullest extent permitted by law, by final, binding and confidential arbitration by a single arbitrator conducted in New York, New York by Judicial Arbitration and Mediation Services Inc. ("***JAMS***") under the then applicable JAMS rules (at the following web address: https://www.jamsadr.com/rules-employment-arbitration/); provided, however, this arbitration provision shall not apply to sexual harassment and

discrimination claims to the extent prohibited by applicable law that is not preempted by the FAA. A hard copy of the rules will be provided to Executive upon request. A hard copy of the rules will be provided to Executive upon request. **By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this Agreement) shall be decided by a federal court in the State of New York. However, procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. Executive and the Company shall equally share all JAMS' arbitration fees. To the extent JAMS does not collect or Executive otherwise does not pay to JAMS an equal share of all JAMS' arbitration fees for any reason, and the Company pays JAMS Executive's share, Executive acknowledges and agrees that the Company shall be entitled to recover from Executive half of the JAMS arbitration fees invoiced to the parties (less any amounts Executive paid to JAMS) in a federal or state court of competent jurisdiction. Except as modified in the CIIAA, each party is responsible for its own attorneys' fees. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. To the extent applicable law prohibits mandatory arbitration of sexual harassment or discrimination claims and is not preempted by the FAA, in the event Executive intends to bring multiple claims, including a sexual harassment or discrimination claim, the sexual harassment and/or discrimination claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

10. GENERAL PROVISIONS.

10.1 Representations and Warranties. Executive represents and warrants that Executive has provided a true and correct copy of all restrictive covenants governing his employment with Turnstone Biologics to the Company and believes that he is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. The CEO represents and warrants that he is authorized to enter into this Agreement by and on the Company's behalf and that the Company will not require Executive to provide any services prior to the Start Date so that Executive can meet his obligations under his agreements with Turnstone Biologics.

10.2 Advertising Waiver. Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company in which Executive's name and/or pictures of Executive appear. Executive hereby waives and releases any claim or right Executive may otherwise have arising out of such use, publication or distribution.

10.3 D&O Insurance. Executive shall be entitled to indemnification from the Company pursuant

to, and in accordance with the terms of, (i) the Company's charter and bylaws, to the extent that indemnification of Executive is provided for therein, and (ii) any D&O insurance policy covering Executive purchased by the Company.

10.4 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

10.5 Miscellaneous. This Agreement, along with the CIIAA, constitutes the complete, final and exclusive embodiment of the entire agreement between Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both Executive and a duly authorized member of the Board. This Agreement will bind the heirs, personal representatives, successors and assigns of both Executive and the Company, and inure to the benefit of both Executive and the Company, and to his and its heirs, successors and assigns. The provisions of this Agreement shall survive the termination of Executive's employment to the extent necessary to effectuate the post-termination obligations contained herein, including but not limited to the Company's obligation to make severance payments (if applicable) or provide indemnification and the Executive's obligations to comply with the CIIAA and any Release. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New York. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties have executed this Agreement as of the day and year first written above.

IN8bio, Inc.

By: _
Name: William Ho
Title: President & CEO

Accepted and agreed:

/s/ Patrick McCall

_____
Patrick McCall

Exhibit A

Permitted Non-Company Positions

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-249530) of IN8bio, Inc. of our report dated March 17, 2022, on our audits of the financial statements of IN8bio, Inc. as of December 31, 2021 and 2020 and for the years then ended, which report appears in this Annual Report on Form 10-K of IN8bio, Inc. for the year ended December 31, 2021.

/s/ CohnReznick LLP

Tysons, Virginia
March 17, 2022

Exhibit 31.1

CERTIFICATIONS

I, William Ho, certify that:

1. I have reviewed this Annual Report on Form 10-K of IN8bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2022

/s/William Ho
William Ho
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Patrick McCall, certify that:

1. I have reviewed this Annual Report on Form 10-K of IN8bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2022

/s/ Patrick McCall
Patrick McCall
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), William Ho, Chief Executive Officer of IN8bio, Inc. (the "Company"), and Patrick McCall, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned have set their hands hereto as of the 17 day of March, 2022.

/s/ William Ho	/s/ Patrick McCall
William Ho	Patrick McCall
Chief Executive Officer	Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of IN8bio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.