2022 Annual Report

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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, 2022

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the fi ling reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1 ☐

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 $2.26 per share of the Registrant's common stock as reported on the Nasdaq Stock Market LLC on June 30, 2022, the last business day of the Registrant's most recently completed second quarter was $5.9 million. This calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 29, 2023 was 24,938,058.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2023 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, 2022.

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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," "Cancer Zero," 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 and the image found on page 28 of this Annual Report was from BioPharma Dealmakers, March 2023.

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 ability to mitigate the substantial doubt to continue as a going concern;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- 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 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;
- our expectations regarding the impact of recent bank closures, public health crises and geopolitical tensions, such as the Russia-Ukraine war, on our business, our industry and the economy;
- our ability to contribute to eliminate cancer and achieve cancer-free status in any or all patients; 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.

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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 product candidates for solid and liquid tumors. Gamma-delta T cells are a specialized population of T cells that possess unique properties. They are naturally occurring immune cells that 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, induced pluripotent stem cell, or iPSC and genetically modified cell therapy approaches that are designed to effectively identify and eradicate tumor cells. We are the most clinically advanced gamma-delta T cell focused cellular therapy company and are utilizing our suite of DeltEx platform technologies as we aspire to eliminate cancer cells to achieve our mission of what we refer to as Cancer Zero ─ the elimination of all cancer cells in every patient battling the disease. We believe this lofty aspiration will one day be achievable, and that it's our responsibility to directly contribute to related global health efforts by pursuing scientific research that will advance cancer treatment.

Pursuant to a company-sponsored investigational new drug application, or IND, cleared by the FDA in late 2022, we plan to initiate a Phase 2 clinical trial of our lead product candidate, INB-400, for the treatment of newly diagnosed glioblastoma, or GBM, in the second half of 2023. This trial will expand the assessment of autologous, genetically modified gamma-delta T cells in newly diagnosed GBM patients across multiple centers across the country. We expect this will confirm the efficacy signal suggested by the investigator initiated trial INB-200. We are also seeking to complete two on-going Phase 1 clinical trials: INB-200 for the treatment of newly diagnosed 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 complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024. For INB-100, we expect to complete enrollment of the Phase 1 clinical trial and determine the recommended Phase 2 dose, or RP2D in 2023, with updated results throughout 2023 and topline results in 2024. In addition, in the second half of 2023 we plan to submit an IND to initiate our Phase 1b clinical trial of INB-410 in which allogeneic, genetically modified gamma-delta T cells will be assessed in both relapsed and newly diagnosed GBM patients.

We also have a portfolio of preclinical programs in development, including INB-300, which focuses on addressing various solid and liquid tumors using a dedicated gamma-delta non-signaling chimeric antigen receptor T cell, or nsCAR construct. We expect to present additional preclinical data demonstrating our proof-of-concept and the ability for a nsCAR construct to distinguish between tumors and healthy tissue at the American Association of Cancer Research, or AACR annual meeting in 2023.

In May 2022, we unveiled the expansion of our DeltEx platform capabilities to include iPSC derived gamma-delta T cells. iPSCs represent a significant step toward next generation approaches of cellular manufacturing for true allogeneic and potentially 'off-the-shelf' innate cell therapies. We intend to continue to advance our internal research, including the application of our proprietary DeltEx technologies into additional solid tumor indications, which we expect to announce in the first half of 2023. We plan to file several company-sponsored IND applications for our pipeline product candidates over the next few years.

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 kill tumors rapidly and directly. Chemotherapy, however, can also result in residual tumor cells that are chemotherapy resistant which leads 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. 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 tumor cells and cancer stem-cells, by attacking at the time when the tumor is experiencing maximum chemotherapy-induced stress and vulnerability. We have termed this chemotherapy resistant cell therapy 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 and are currently one of only two companies known to have produced gamma-delta T cells from iPSCs. In addition, we believe we are the only company to have demonstrated the ability to use directed differentiation to derive both Vdelta1+, or Vd1+ and Vdelta2+, or Vd2+ gamma-delta T cells sub-populations from iPSCs. In order to develop potentially off-the-shelf therapies in the future, 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 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 capitalizes on the particular properties of gamma-delta T cells. We have advanced three 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, iPSC and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

Going Concern

The report from our independent registered public accounting firm for the year ended December 31, 2022, includes an explanatory paragraph stating that our recurring losses since inception raises substantial doubt about our ability to continue as a going concern. Our existing cash will not allow us to fund our operations past mid-July of 2023, which includes reserves for all necessary winddown expenses. We have taken measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy, including our ability to achieve the anticipated milestones for our preclinical and clinical programs. To continue to fund our operations, management has developed plans, which primarily consist of raising additional capital through some combination of equity and/or debt offerings, including through our ATM program, and identifying strategic collaborations, licensing or other arrangements to support development of our product candidates. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed, that management will be able to obtain financing or enter into a collaboration on terms acceptable to us, or that any additional financing or revenue generated through third-party collaborations will be sufficient to fund our operations.

If additional capital is not available to us on a timely basis, or at all, we will be required to take additional actions beyond the cost preservation measures initiated to address our liquidity needs, including to explore other strategic options, continue to further reduce operating expense or to delay, reduce the scope of, discontinue or alter our research and development activities. If we do not obtain additional financing and are required to terminate our operations, our stockholders will lose their investments.

Our Pipeline

The following chart shows the developmental status and the next anticipated milestones of our clinical and preclinical product candidates, all of which are wholly owned. The timing of the next anticipated milestones below and the related discussion throughout this Business section are estimates based upon the receipt of additional capital to fund our programs. See "—Going Concern" for additional information:

Figure 1. Pipeline Chart

INB-200 is a genetically modified autologous gamma-delta T cell product 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, demonstrate the ability of 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 median overall survival has remained at 14 to 16 months 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 DeltEx DRI gamma-delta T cells. We expect to complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024.

INB-100, our first 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 hematologic malignancies that are undergoing allogenic 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 complete enrollment of the Phase 1 clinical trial and determine the RP2D in 2023, with updated results throughout 2023 and we expect to have topline results in 2024.

INB-400 is in a Phase 2 clinical trial using our autologous DeltEx DRI product candidate to treat newly diagnosed GBM. Our IND was cleared by the FDA in December 2022. The INB-400 clinical trial will further confirm the clinical efficacy of autologous DeltEx therapy in a large national multicenter trial. We currently expect to initiate patient enrollment in the second half of 2023 and report initial data from the Phase 2 clinical trial in 2025. Per FDA Guidance for Industry finalized on November 4, 2022, allogeneic product candidates constitute a separate drug product and require a separate IND. INB-410 will evaluate the

safety of genetically modified, allogeneic DeltEx DRI gamma-delta T cells in both the relapsed and newly diagnosed GBM patient populations. Clinical data and experience from the Phase 1 clinical trials of INB-200 and INB-100 will be utilized to support submission of an IND for INB-410, which is expected in the second half of 2023. We believe this is the first time a similar gene-edited construct has been tested in both the autologous and allogeneic settings. Eventually, we expect this DeltEx DRI approach will be assessed in a broader range of solid tumor cancers and we currently expect to announce the first extra-cranial solid tumor indication for this program in the first half of 2023.

We are also developing a broad portfolio of preclinical programs utilizing the unique biology of gamma-delta T cells in our efforts to achieve our mission of Cancer Zero. INB-300 is a preclinical program focused on developing unique nsCAR-enabled DeltEx product candidates with which we expect to target difficult liquid tumors and extracranial solid tumors. The current generation of CAR-T products on the market and in development seek and destroy specific antigen targets such as CD19, CD20, BCMA, CD33, and CD123 among others. These CAR-Ts eliminate tissues expressing the target irrespective of whether they are tumor or healthy tissues. Early data from the CD19 CAR-Ts demonstrate that they drive aplasia of the normal and malignant B-cell compartment. This becomes problematic as many selected antigen targets are also expressed on healthy tissues that are crucial for the continuation of life, especially in solid tumor cancers. Our gamma-delta based nsCAR technology is focused on addressing this challenge in various solid and liquid tumors. Our nsCAR platform uses the innate immune recognition of gamma-delta T cells to distinguish between tumor and healthy tissue, offering a targeted but potentially less toxic approach. These constructs lack a CD3z signaling domain that would typically force T cell activation through the CAR and antigen binding domain. Instead, this T cell utilizes the CAR to localize to the target tumor cells and T cell activation is triggered by the endogenous receptors of the gamma-delta T cell including NKG2D, CD16, toll-like receptors, and gamma-delta TCR among others to actually induce killing of the target tumor cells. The nsCAR platform has demonstrated a greater than 15x difference in killing between leukemic cells and healthy B cells (effector to target, or E:T, ratio=2:1, 79.7% versus 5.2%) when both express the CD19 target antigen. The nsCAR platform is also engineered to express the cytokine interleukin-15 (IL-15) to enhance cellular persistence and the ability to target and kill tumor cells over time. We believe that the platform has the potential to broaden the utilization of CAR technology for previously "undruggable" solid and liquid tumor targets. Additional internal programs are focused on advanced manufacturing methodologies such as iPSCs and on logical combinations with other therapies approved by the FDA.

As of December 31, 2022, 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 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 in our efforts to achieve our mission of Cancer Zero. To achieve this goal, our strategy is as follows, which is dependent on our ability to raise additional capital or successfully deploy other strategic options:

- ***Continue advancing our lead clinical product candidates, INB-400, INB-200 and INB-100.*** INB-200 is our autologous DeltEx DRI program that we are initially developing for the treatment of newly diagnosed GBM. We are conducting a Phase 1 dose-escalation clinical trial assessing single and multiple dosing schemas at UAB. We expect to complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024. We are conducting a Phase 2 multi-center clinical trial of INB-400, our company-sponsored clinical program using our autologous DeltEx DRI product candidate to treat newly diagnosed GBM. We currently expect to initiate patient enrollment in the second half of 2023 and report initial data from the Phase 2 clinical trial in 2025. We are also conducting a Phase 1 dose escalation clinical trial of INB-100, our allogeneic DeltEx product candidate in leukemia patients undergoing allogeneic HSCT, from which we currently expect to complete enrollment of the Phase 1 clinical trial and determine the RP2D in 2023, with updated results throughout 2023 and topline results in 2024.
- ***Advance INB-500, INB-410 and INB-300 into clinical development, subject to receiving authorization from FDA pursuant to company-sponsored INDs.*** With additional capital, we expect to file a new IND for INB-410, a genetically modified allogeneic DeltEx DRI cell product for relapsed and newly diagnosed GBM, in the second half of 2023. INB-300 is a DeltEx nsCAR construct, for which we are testing various antigen recognition domains in our efforts to advance a program to IND enabling studies. We expect to present initial data demonstrating proof-of-concept for this program in the first half of 2023. INB-500 is the expansion of our DeltEx platform capabilities to include iPSC

derived gamma-delta T cells. Our feeder cell and serum free expansion and differentiation protocols have demonstrated an ability to generate both Vd1+ and Vd2+ gamma-delta T cell subclones. These cells have high-cytotoxicity, and we are exploring avenues for advancement and potential partnering.

- ***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 and INB-400, including in combination with other therapeutics and in other solid tumors outside of GBM, over the next several 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 such as the Dunbar CAR-T Cell Program at the University of Louisville 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 groups of 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.

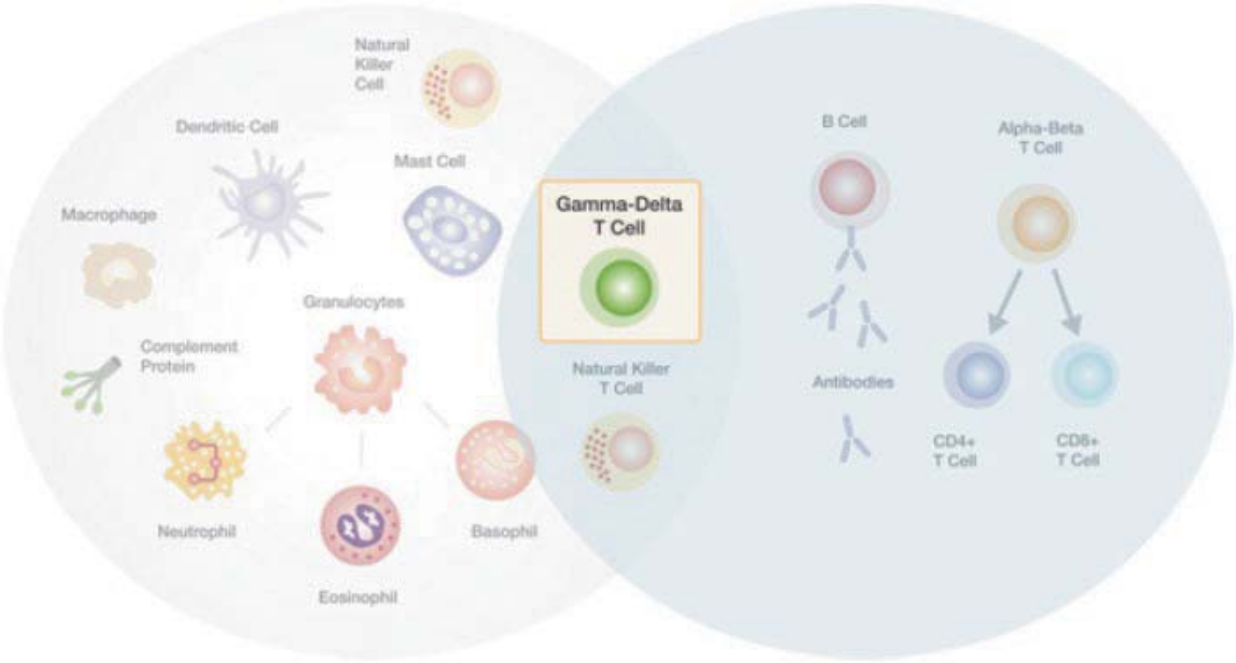


Figure 2. Gamma-Delta T Cells: Innate and Adaptive Immune System Characteristics

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, KYMRIAH®, 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 to generate a high effector to target, or E:T ratio, 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, a limited ability to efficiently introduce genetic modifications, and lower cell persistence. 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 traditional CAR-T. More recently, early CAR-NK cell clinical data has generated increasing uncertainty about the persistence of NK cell based cellular therapies and their durability of response. These observations have resulted in significant pipeline changes and the termination of multiple programs by three major biotechnology companies developing NK or iNK cell therapies in early 2023.

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 tumor microenvironment, or TME, approximately 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.

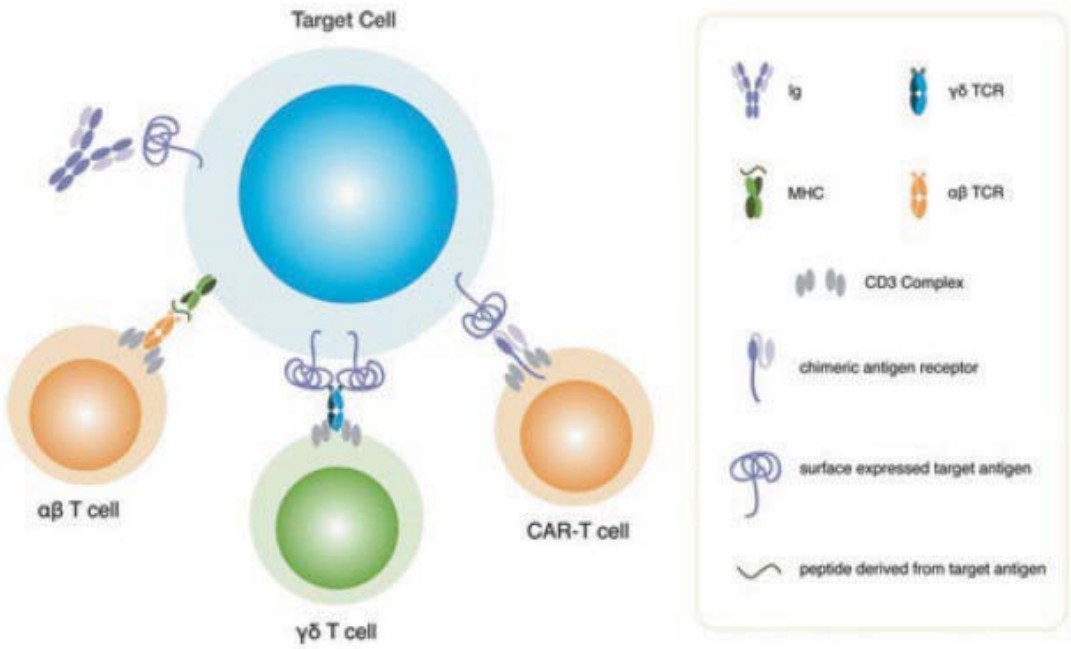


Figure 3. "Nature's CAR-T Cell"

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, their diverse receptor repertoire may enable them to recognize and target the array of heterogeneous 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.

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.

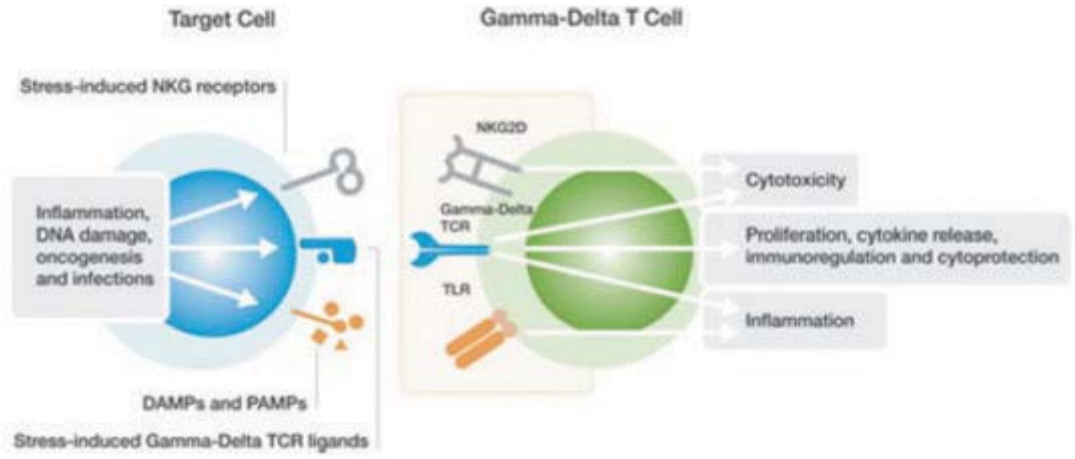


Figure 4. Innate Immune Cell Receptors of Gamma-Delta T Cells

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 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.

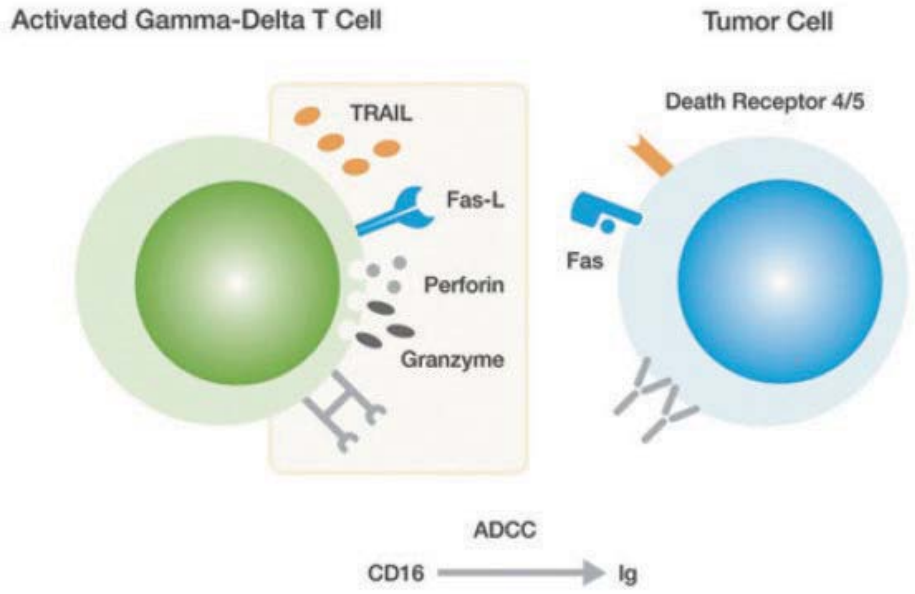


Figure 5. Multiple Cell-Killing Mechanisms of Activated Gamma-Delta T Cells

Opportunities for Gamma-Delta T Cells in Cancer

The therapeutic potential of gamma-delta T cells is supported by observations over 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 scientific 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, 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, grafts from a partially matched donor increased in those with high levels of gamma-delta T cells. These findings have been supported by reported studies from other scientists. In 2007, Dr. Lamb and his collaborators found that the association between post-transplant gamma-delta T cells and survival as depicted in Figure 6 below, 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.

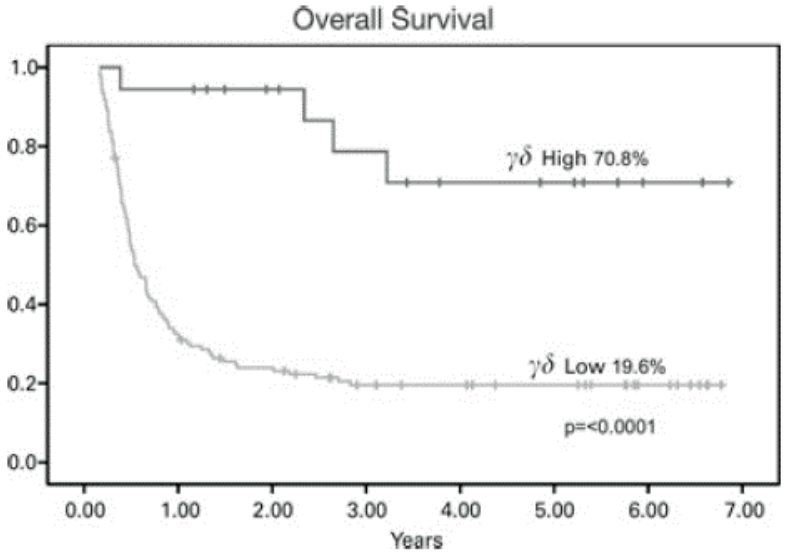


Figure 6. Correlation of Naturally Occurring Gamma-Delta T cells and Long-Term Survival in Leukemia

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.

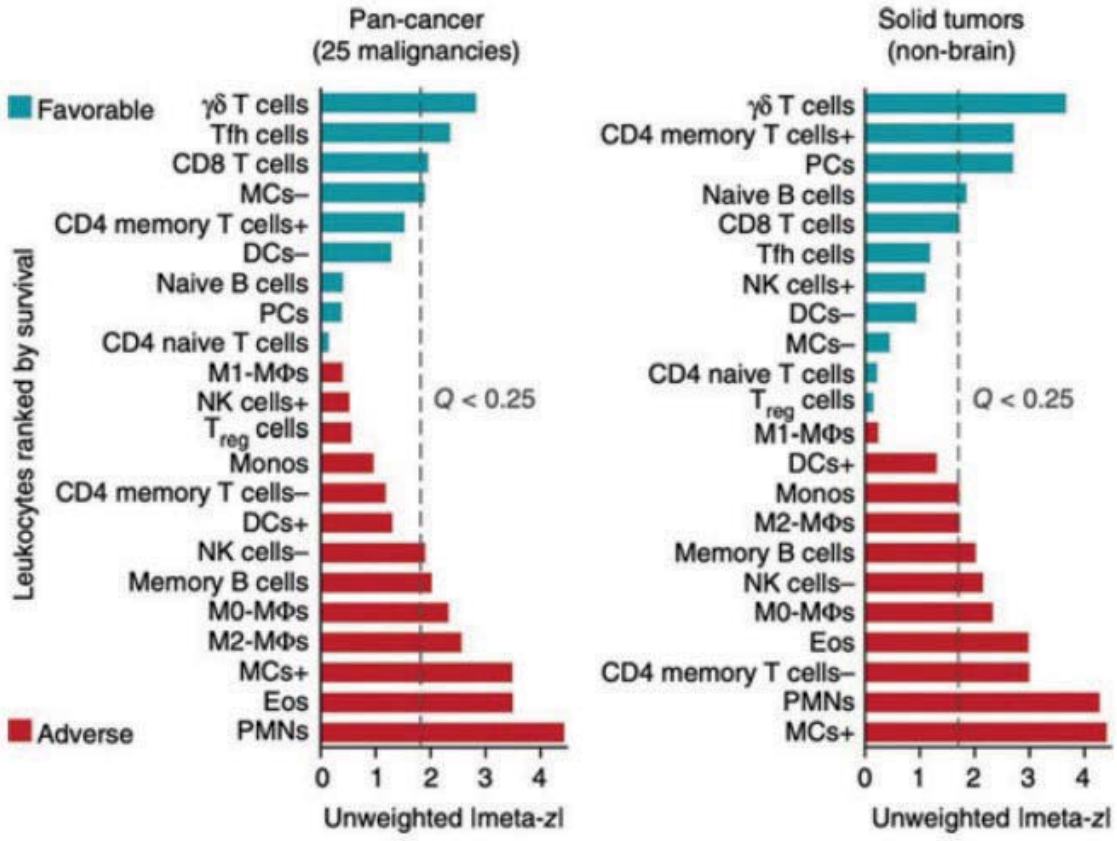


Figure 7. Prognostic Association of Tumor Infiltrating Lymphocytes and Survival Outcomes

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 cellular therapies. 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, iPSC 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 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 while preserving healthy tissue. 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 were 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 our current 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.

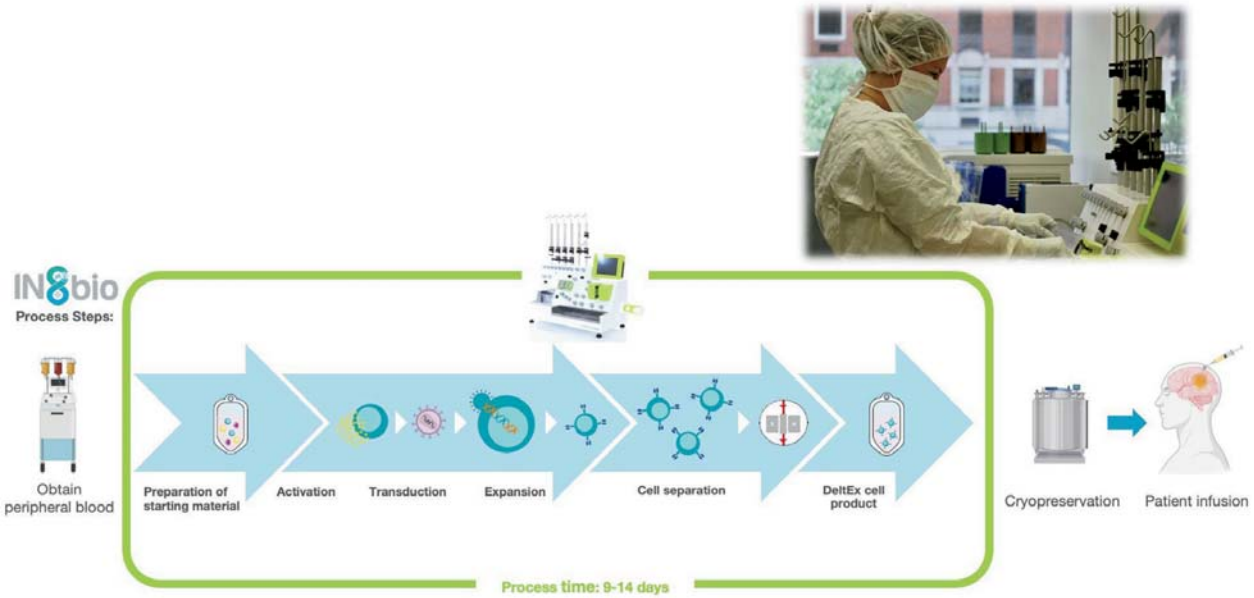


Figure 8. Reproducible & Scalable Manufacturing Process

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, and the Vdelta1 positive. 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 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 which recover following lymphodepletion within approximately 15 to 30 days. 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 2001. 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 radiation 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 complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024.

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 13,000 new cases having been estimated in 2022. 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 to 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 local microscopic residual tumor cells that were 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.

We also intend to investigate TMZ in combination with other chemotherapies in the future, which 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 to the tumor site. A 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 systemic 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 21 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 placed in the resection cavity of the tumor. 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 induction TMZ and radiation therapy, followed by maintenance TMZ in combination with INB-200, as shown in Figure 9 below. During resection, an intracranial catheter (Rickham 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.

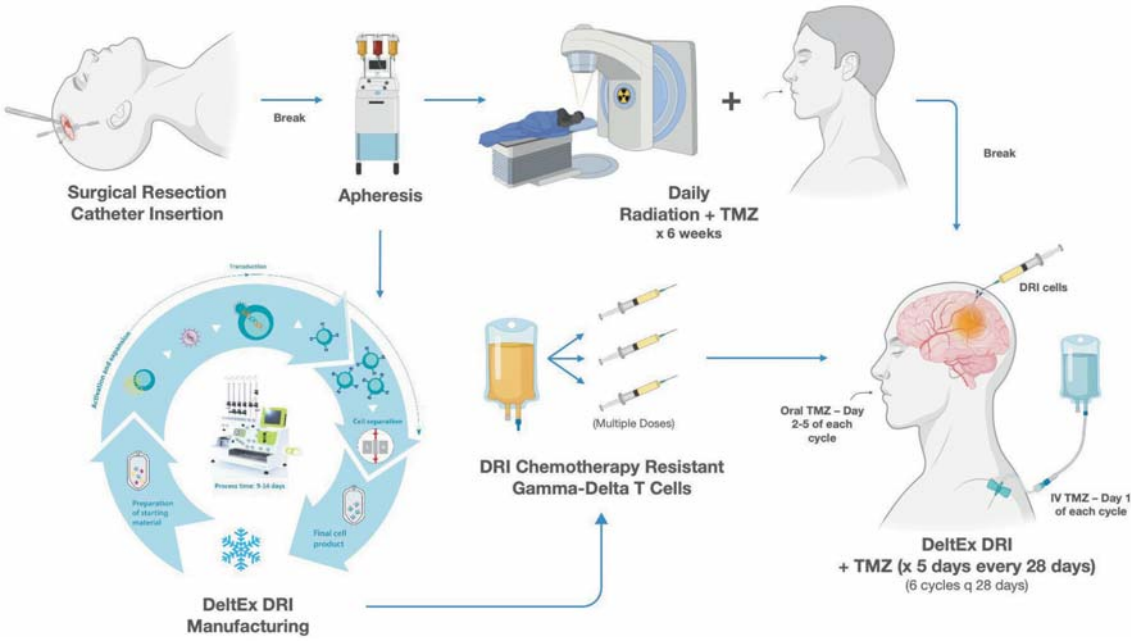


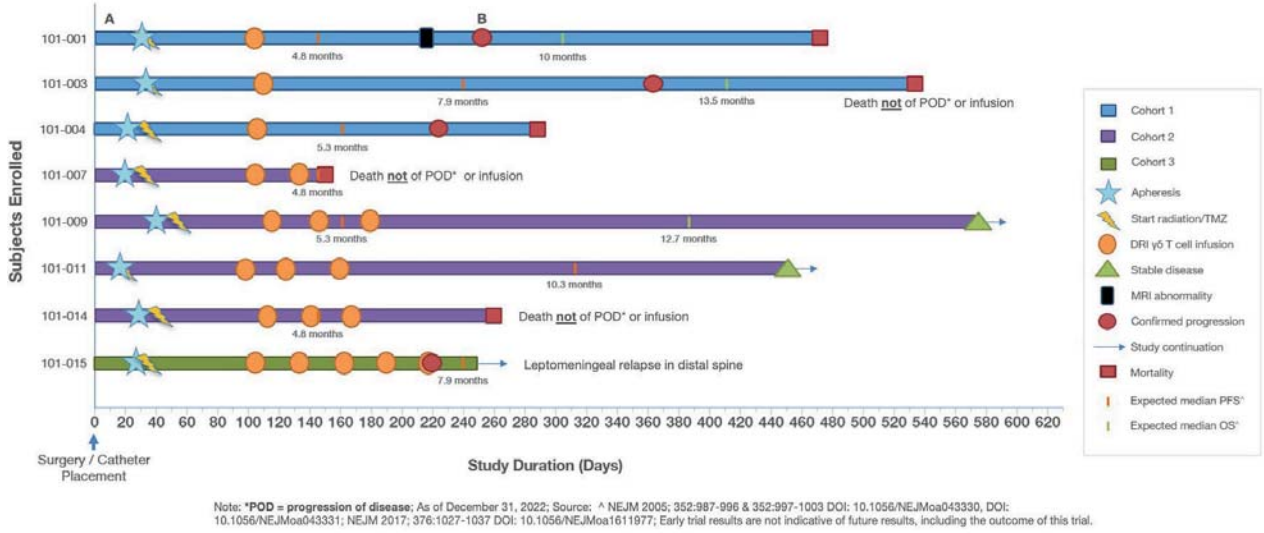
Figure 9. INB-200 Administration Protocol

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 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. Standard-of-care 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 six injections of INB-200.

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

Fifteen patients with newly diagnosed GBM have been enrolled in this trial and a total of eight patients have received treatment as of December 31, 2022. Cohorts 1 and 2 have completed enrollment while enrollment in cohort 3 remains on-going with one patient undergoing dosing and continuing to be monitored. No infusion reactions, CRS, neurotoxicity, or other dose limiting toxicities, or DLTs, or treatment-related series adverse events, or SAE, or treatment-emergent adverse events, or AE, were observed in the first or second cohorts to date, allowing us to proceed to Cohort 3. The patients in Cohort 1 each received a single dose of INB-200, following a minimum of 30 days for safety observation. The three patients comprising the first dose cohort received a single dose of INB-200, and all patients have died, one due to infection from a pancreatic cyst and two due to progression of disease. Two patients remained alive through 15.6- and 17.7-months post-treatment, having exceeded both their expected progression free survival, or PFS, and overall survival, or OS, respectively. In Cohort 2, four patients have been dosed, with two who remain progression free at 18.9 and 14.8 months, while a third died without relapse due to a non-treatment-related AE of pulmonary embolus at 8.7 months. As previously disclosed, the first Cohort 2 patient died of an acute cardio-pulmonary

event 22 days after receiving their second infusion, which was deemed unrelated to treatment with INB-200 and also died without evidence of disease. The two surviving patients continue to exceed the median survival for GBM patients with the standard Stupp regimen, suggesting that increasing doses of gamma-delta T cells may favor longer PFS and OS. One Cohort 3 patient has completed 5 of 6 planned doses without any DLTs. The patient has no local GBM relapse, which is typical in 99% of GBM cases, but does have evidence of distal leptomeningeal disease, which occurs in approximately 0.4% of patients. Following treatment, all patients will be monitored for biologic correlates, time to disease progression and overall survival. We expect to complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024. The most common AEs were Grade 1/2 events including fever, fatigue, nausea, headache, platelet count decreased, incision site pain attributable to TMZ, radiotherapy or disease. One subject had Grade 3 treatment unrelated AEs of urinary tract infection, dehydration, and thrombocytopenia.



Note: *POD = progression of disease; As of December 31, 2022; Source: ^ NEJM 2005; 352:987-996 & 352:997-1003 DOI: 10.1056/NEJMoa043330, DOI: 10.1056/NEJMoa043331; NEJM 2017; 376:1027-1037 DOI: 10.1056/NEJMoa1611977; Early trial results are not indicative of future results, including the outcome of this trial.

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, 2022. Early data demonstrate 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. We are actively recruiting additional patients into Cohort 3. We currently expect to complete enrollment of Cohort 3 in 2023, with clinical updates expected throughout 2023 and expect to have long-term follow-up data in 2024.

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.

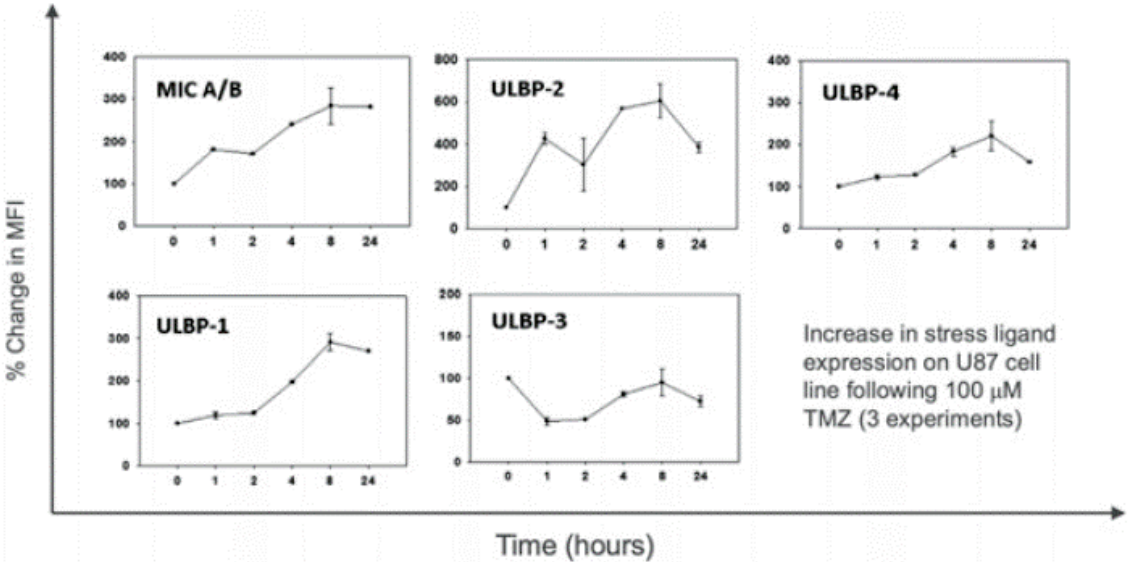


Figure 12. Increased NKG2D Ligand Expression Observed on TMZ-Resistant Tumor Cells Treated with TMZ

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

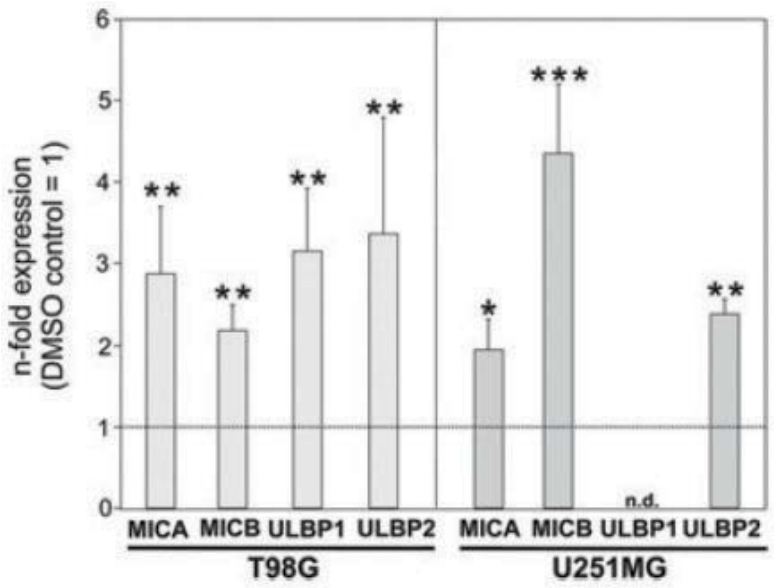


Figure 14. Increased NKG2D Ligand Expression in Glioma Stem Cells Treated with TMZ

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.

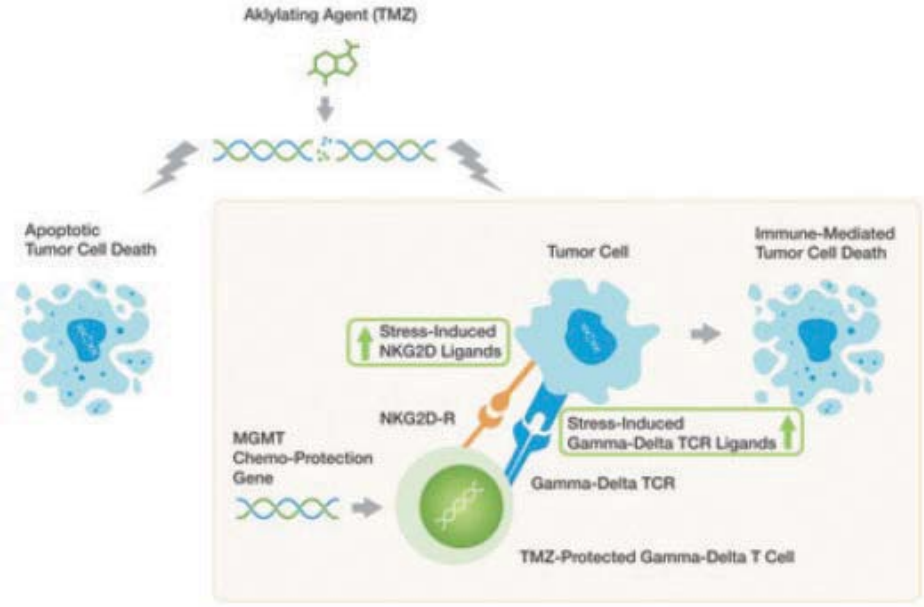


Figure 15. DeltEx DRI Mechanism of Action Targeting the DNA Damage Response (DDR)

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.

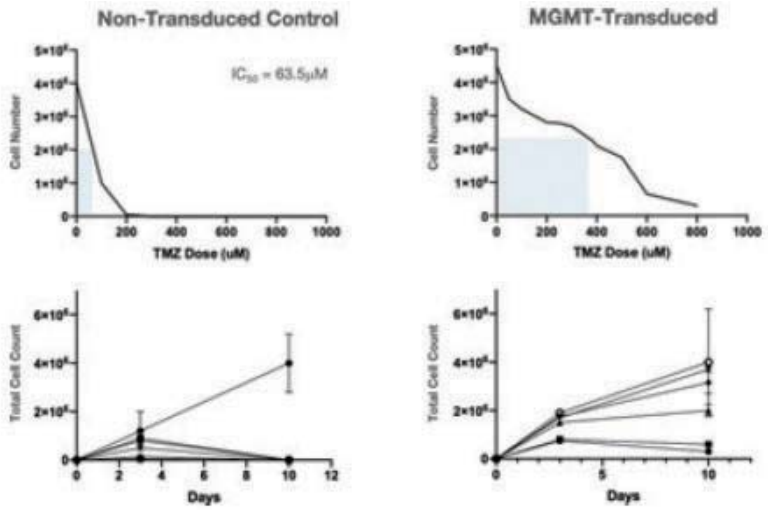


Figure 16. MGMT-Modified Gamma-Delta T Cells Demonstrate Protection Against Killing Effects of TMZ

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.

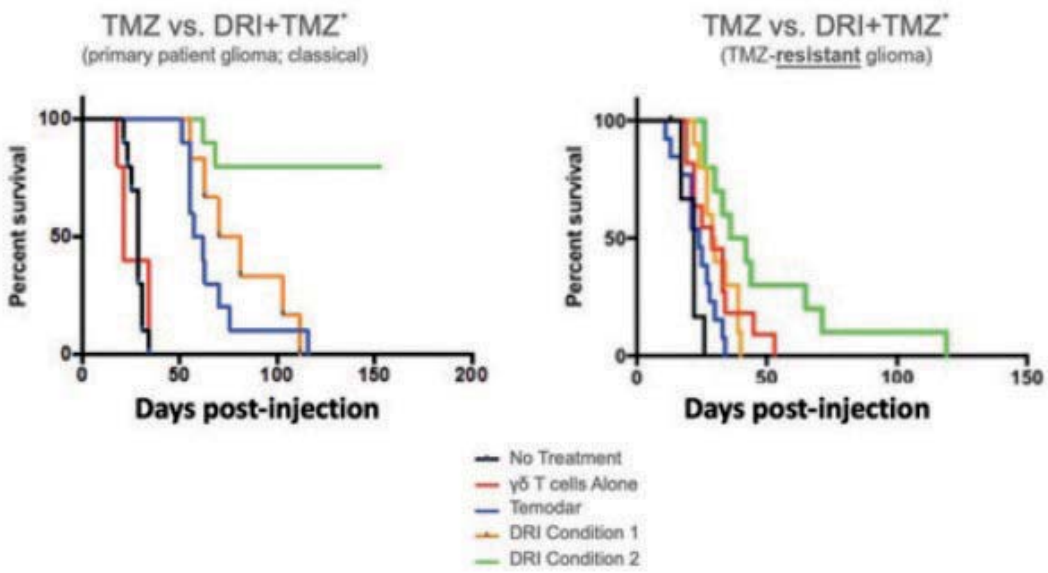


Figure 17. Improved Survival Observed in Both TMZ-Sensitive and TMZ-Resistant GBM Models

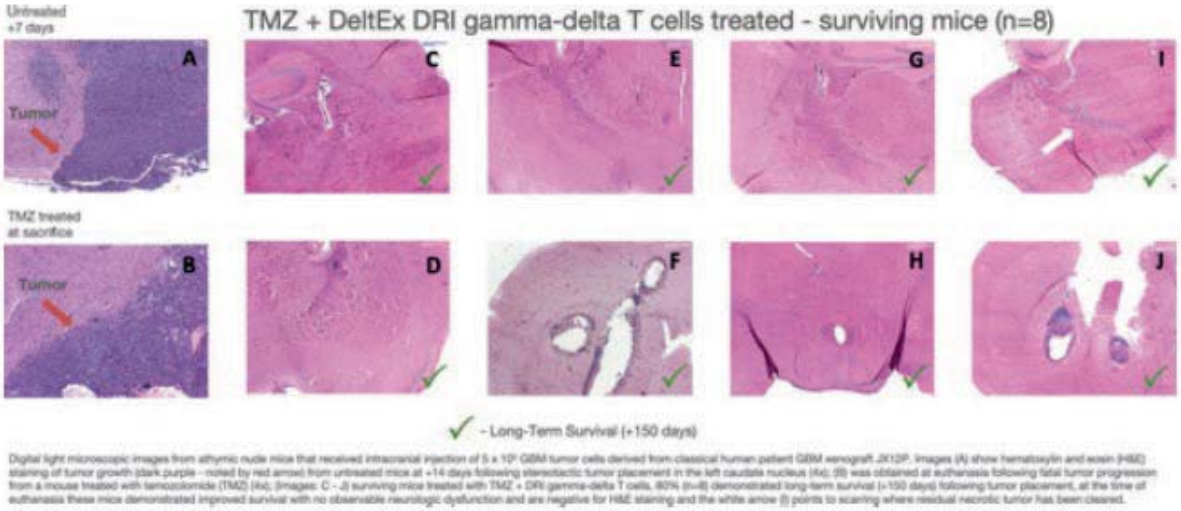
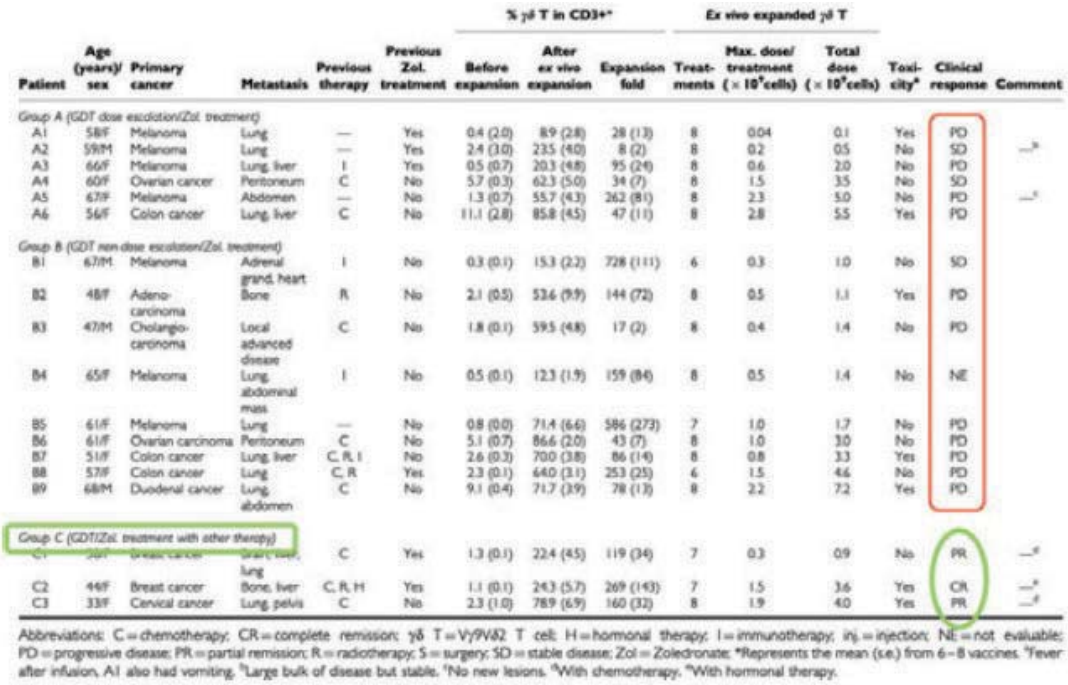


Figure 18. Histopathology Demonstrates No Residual GBM in Mice

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.



Patient	Age (years)/ sex	Primary cancer	Metastasis	Previous therapy	Previous Zol. treatment	% γδ T in CD3+* Before expansion	% γδ T in CD3+* After ex vivo expansion	% γδ T in CD3+* Expansion fold	Ex vivo expanded γδ T Treatments	Ex vivo expanded γδ T Max. dose/ treatment (× 10^9cells)	Ex vivo expanded γδ T Total dose (× 10^9cells)	Toxicity*	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	—[a]
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	—[a]
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 gland, 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	26/F	Breast cancer	Brain, liver, lung	C	Yes	1.3 (0.1)	22.4 (4.5)	119 (34)	7	0.3	0.9	No	PR	—[a]
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	—[a]
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	—[a]

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. The 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 Phase 2 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, 2022, we have treated six patients in this trial with all six patients remaining in morphologic complete remission, or CR, including two patients for periods greater than two years and one patient for a period 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 once they have progressed on standard-of-care first line therapies. 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 8,000 patients treated in the United States in 2020.

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.

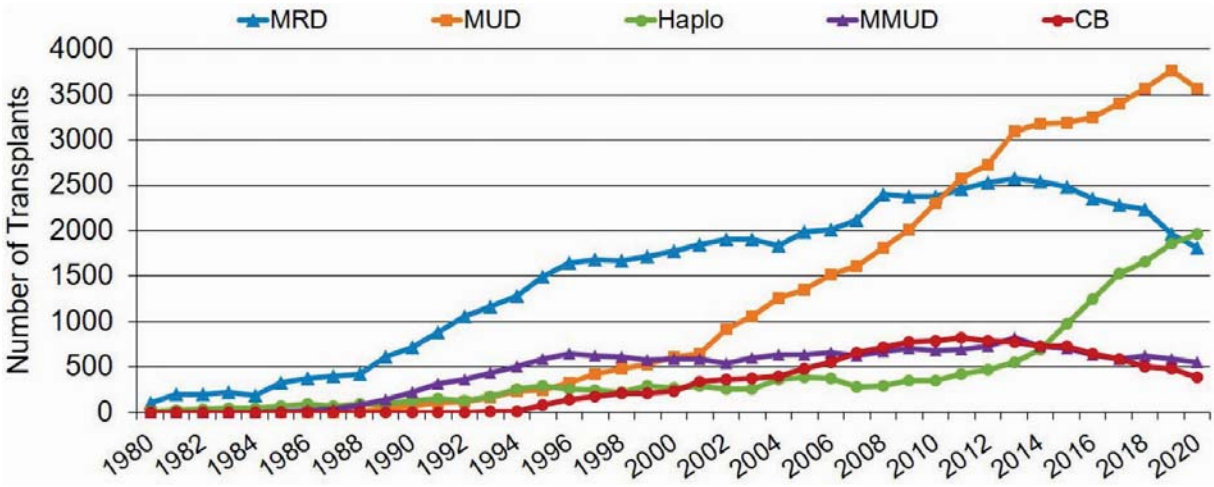


Figure 20. Number of Allogeneic HCTs in the US by Donor Type

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 and are the fastest growing type of HSCT in the U.S.

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 testing the safety of allogeneic gamma-delta T cells and 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. We have since 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 hematologic malignancies 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 a total of 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.

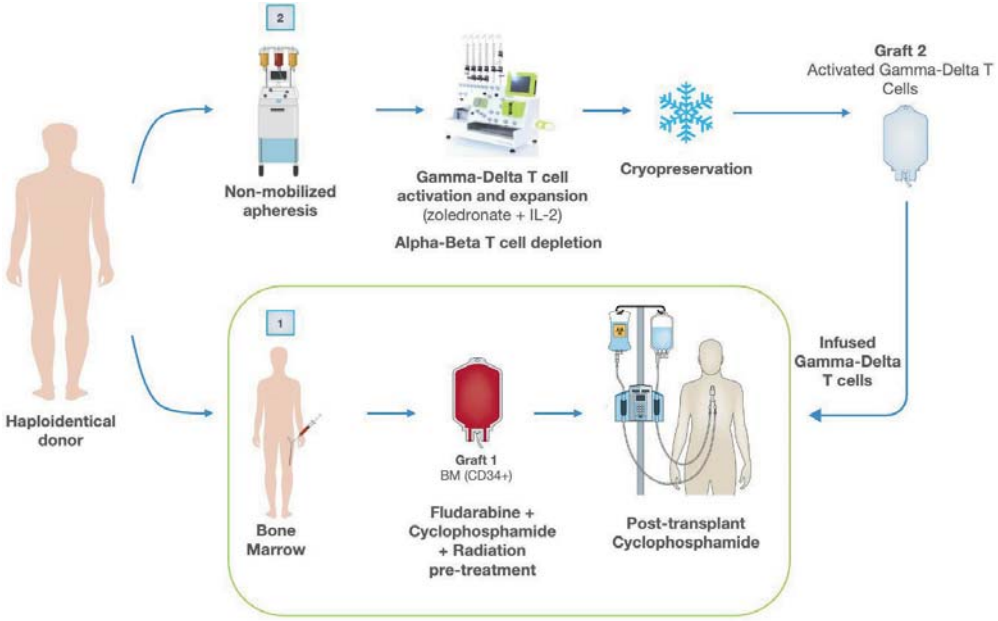


Figure 21. INB-100 Administration

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 is approximately 51% at one year and even greater in those patients with high-risk and/or complex cytogenetics. 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.

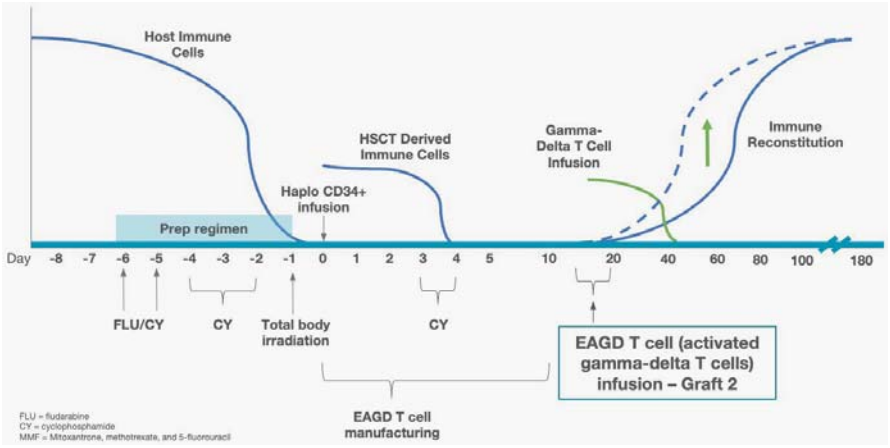


Figure 22. The Projected Composition of Patient's Systemic Immune Cells in the INB-100 Phase 1 Trial

As represented in Figure 23 below, as of December 9, 2022, six patients have been enrolled in this trial and infused with INB-100, our DeltEx Allo therapeutic candidate. Six 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. One patient was dosed with a suboptimal dose of cells and not considered evaluable for safety or efficacy but has been the only patient who received any INB-100 who has relapsed and/or died to date. The four patients treated in Cohort 1 with relapsed AML demonstrate that allogeneic gamma-delta T cell therapy has a manageable toxicity profile with the potential for durable remissions in high-risk patients. Three subjects who have been followed for more than one year, remain in morphologic CR at 31.9, 29.5 and 17.8 months, respectively as of the last update on December 9, 2022 at the American Society of Hematology Annual Meeting. Patient 007 treated in Cohort 1 remains in CR at 3.5 months while two additional patients treated in Cohort 2 (receiving a dose of $3x10^6$ cells/kg) remain in CR at 1.4 and 1.2 months, respectively.

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, or ICANS. All patients have sustained steroid responsive grade 1-2 skin GvHD while three patients reported grade 1-2 gastrointestinal GvHD that resolved with steroid therapy. No events of grade 3 or greater GvHD, cytokine release syndrome or ICANS has been observed.

We expect to complete enrollment of the Phase 1 clinical trial and determine the RP2D in 2023, with updated results throughout 2023 and topline results in 2024.

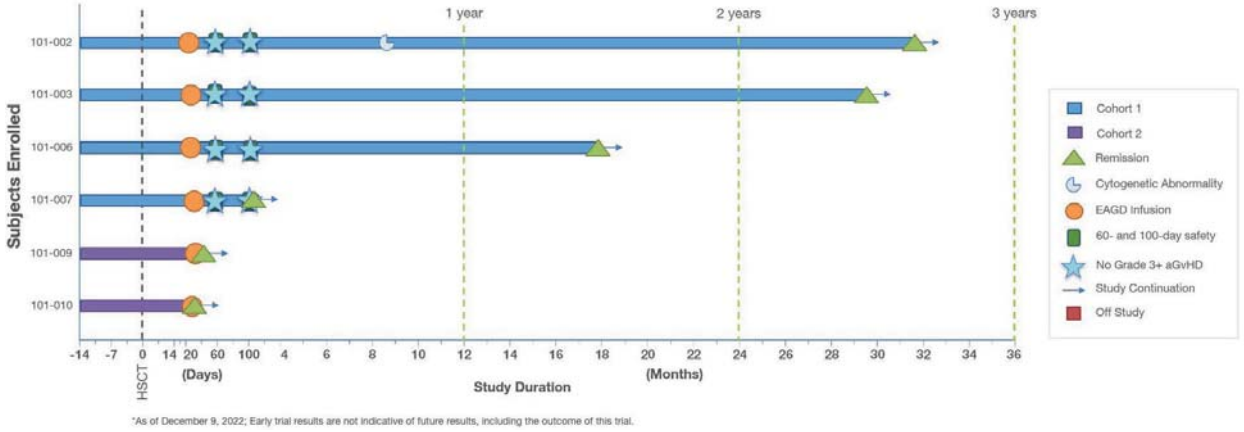


Figure 23. Summary of Patients Treated in INB-100 Phase 1 Trial

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 allogeneic 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 such as flu/cy 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 18 years.

To reach our goal of advancing toward an allogeneic genetically modified product candidate for solid tumors, we are currently pursuing two ongoing Phase 1 clinical trials 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 INB-410, an allogeneic-sourced product for the treatment of GBM and other solid tumor cancers.

Our Additional Product Candidates

INB-400 (Autologous) / INB-410 (Allogeneic): Drug-Resistant Gamma-Delta T Cells

INB-400 and INB-410 are 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. The INB-400 and INB-410 trials will have three cohorts (as represented in Figure 24 below).

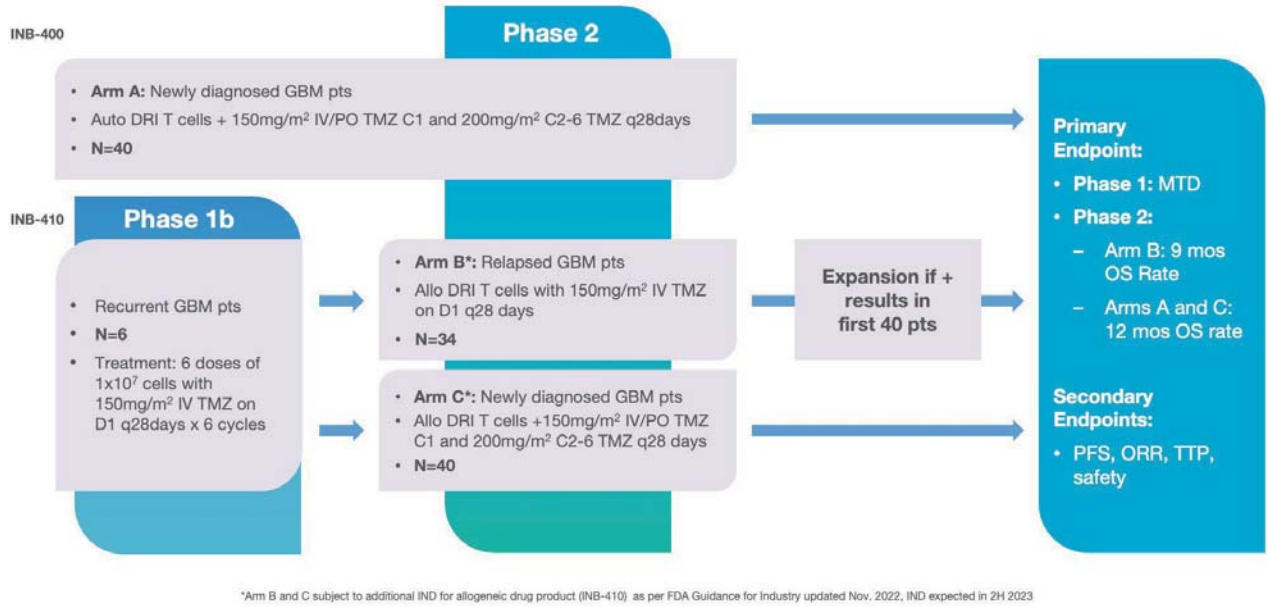


Figure 24. Proposed Clinical Trial Design for INB-400 / INB-410

One cohort consisting of INB-400 (Arm A), 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 INB-410 DeltEx DRI allogeneic cells administered to relapsed GBM patients (Phase 1b). If the initial safety cohort establishes the safety of this modality, two cohorts of patients with either relapsed disease (Arm B) or newly diagnosed disease (Arm C) will receive allogeneic gamma-delta cells (as represented in Figure 25 below). The primary goal of this trial 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 and validation. In addition, the value of an autologous product lies in the paucity of allogeneic donors for all patients, the potential for greater cell persistence and potential cross talk between cell types. Given our experience with INB-100 and the available preclinical data, we expect a low rate of GvHD with the allogeneic product but given the novelty of intracranial delivery of allogeneic cells, the company intends to mitigate risk by also continuing development of the autologous product which appears to have manageable safety while providing evidence of clinical activity. We submitted an IND for the autologous drug product (INB-400) in late 2022, for which clearance was received within the initial 30-day review period by the FDA. With additional funding, we currently expect to submit a supplemental IND supporting the allogeneic drug product (INB-410) in the second half of 2023.

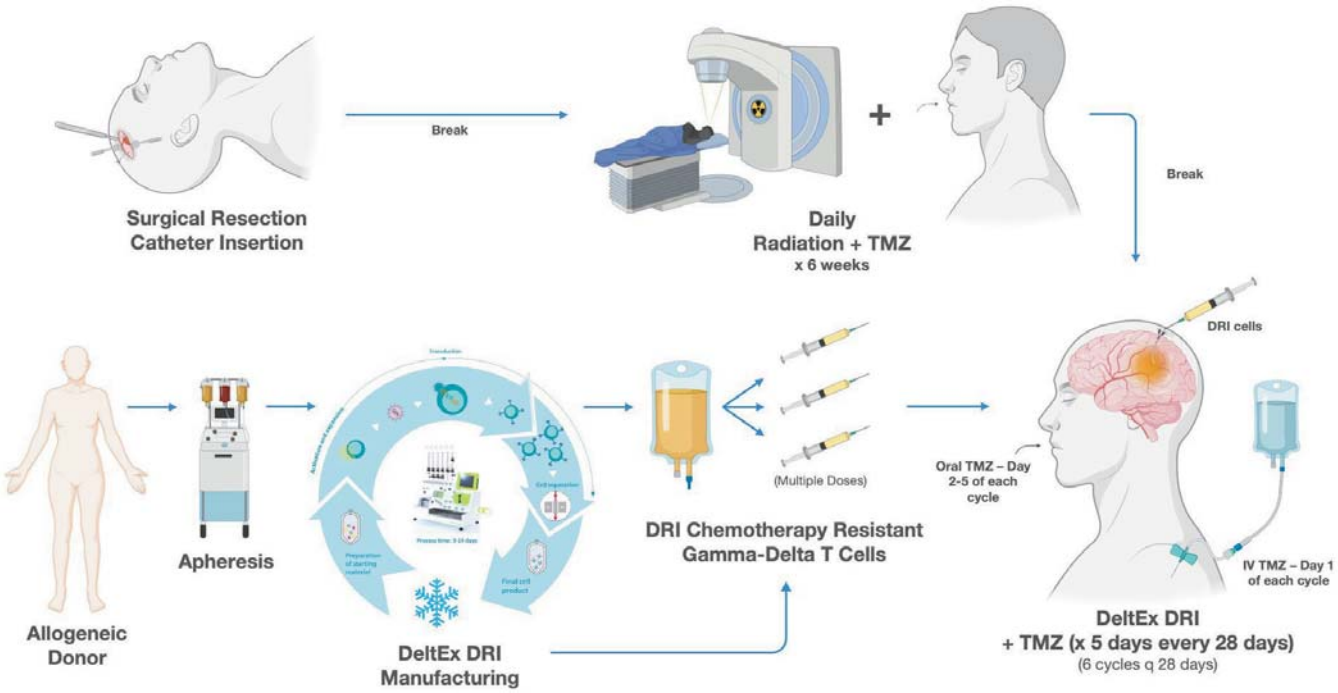


Figure 25. INB-400 Allogeneic Administration

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

INB-300 is our DeltEx DRI and nsCAR gamma-delta T cell preclinical product candidates that combine our expertise in gamma-delta T cells, our DeltEx DRI technology and a novel CAR directed against novel antigen targets. While we have developed a classical signaling CAR-T construct which is cytotoxic, we have also designed novel nsCAR constructs that omit the CD3z signaling domain. This nsCAR allows the modified gamma-delta cells to better traffic to the tumor cells expressing an antigen targeting 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 CAR binding of cells that are not expressing high levels of NKG2D or TCR antigens, i.e., healthy normal tissue, would not result in activated cell killing and thus avoid an unintended cytotoxic response as shown in Figure 26 below, published in the Nature.com article "T cells without limitation" in March 2023.

Additionally, this CAR construct can also incorporate the gene for MGMT from our DeltEx DRI candidate or designed to also secrete cytokines such as IL-15. Thus such nsCAR constructs can be designed to confer both TMZ- resistance and tumor-targeting capability to transduce gamma-delta T cells. 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 antigen binding domain as well as increased persistence.

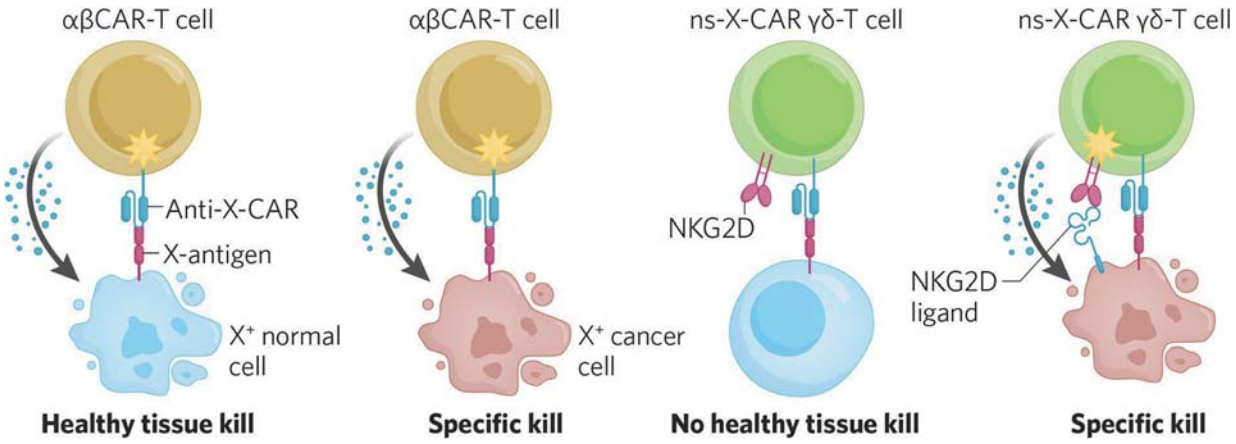


Figure 26. INB-300, a DeltEx Non-Signaling CAR Constructs

INB-500: Induced Pluripotent Stem Cell (iPSC) Derived Gamma-Delta T cells

In May 2022, we unveiled the expansion of our DeltEx platform capabilities to include induced pluripotent stem cell derived gamma-delta T cells. iPSCs represent a significant step toward next generation approaches of cellular manufacturing for true allogeneic and potentially 'off-the-shelf' innate cell therapies. Allogeneic cell therapies offer two distinct and mutually exclusive potential benefits: (i) the ability to treat a cancer patient with cells derived from a younger, healthy individual that likely has greater killing ability, or cytotoxicity, and (ii) the potential ability to replicate billions of cells to treat multiple patients from a single clone derived from a single donor that can be stored and delivered "off-the-shelf." We are testing these potential benefits separately. While our INB-100 program will test and compare the activity of autologous versus allogeneic cells, there remain limits to the expansion capabilities of primary derived gamma-delta T cells. To overcome these limits, we have advanced INB-500, our gamma-delta T cell program based on cells derived from iPSCs.

Cell expansion and therapeutic doses are generally limited by total starting cell count available from a donor, body mass of the recipient, T cell exhaustion during expansion, biologic replication limits due to the Hayflick phenomenon and telomere shortening and limits imposed by regulators due to the potential for cellular transformation. Pharmaceutical guidelines exist to track in vitro cell age as there are phenotypic and genotypic changes that occur with increasing cellular passages and population doubling cycles. Sponsors are required to establish criteria for an upper limit to population doubling level of cells used for production for clinical use. By re-programing cells into a pluripotent, stem-like state, they gain the potential for near unlimited replication. Such cells can be replicated and subsequently differentiated into specific cell lineages, including gamma-delta T cells. To date, we are one of only two companies to have publicly demonstrated an ability to produce gamma-delta T cells from iPSCs. In addition, we believe we are the only company to have demonstrated the ability to derive both Vdelta1+ and Vdelta2+ gamma-delta T cells from iPSCs. We have demonstrated a reproducible expansion process and the ability to genetically engineer our iPSC derived gamma-delta T cells. iPSC derived gamma-delta T cells enable the ability to genetically edit cells and pick specific clones with nearly 100% of cells expressing the gene of interest and to avoid random insertions and/or deletions that can potentially occur with lentivector transductions. Our processes are cell and serum free, and we continue to further develop our expansion capabilities of each subclone and the characterization of such cells.

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 agreements with academic GMP cell therapy labs to manufacture product candidates for our Phase 1 and Phase 2/3 clinical trials. The multi-year agreements allow our medical technologists direct access to the facilities to assist and operate alongside the GMP facility staff. The agreements provides for manufacturing on a per-patient basis. 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 allogeneic and gamma-delta T cell therapy include Acepodia USA, Adicet Bio, Inc., Allogene Therapeutics, Inc., American Gene Technologies International Inc., Astellas Pharma US, Inc., Avalon Globocare Corp., Century Therapeutics, Inc., CytoMed Therapeutics Pte Ltd, Editas Medicine, Inc., Enochian BioSciences, Inc., Eureka Therapeutics, Inc., Gadeta BV, ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Janssen Pharmaceuticals, a division of Johnson & Johnson, Kiromic Biopharma, Inc., LAVA Therapeutics N.V., Leucid Bio Ltd, PhosphoGam Inc., Sandhill Therapeutics, Inc., Shattuck Labs, Inc., Takeda Pharmaceuticals USA, Inc., TC BioPharm Limited, TCR^2 Therapeutics Inc. (which is in the process of a business combination with Adaptimmune Therapeutics plc) and The Bristol-Myers Squibb Company, several of which have initiated 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, 2022, we owned, co-owned or exclusively licensed three issued U.S. patents, four issued European patents, six other issued foreign patents, eight pending U.S. applications, one pending PCT application and 45 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 issued New Zealand patent, 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, one issued Japanese patent, one issued Singaporean patent and nine 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 issued U.S. patent, 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 one pending U.S. application, a PCT application, and a Canadian patent 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.

INB-500

We own one provisional patent application that contains claims and supporting disclosures for methods of generating, producing and genetically modifying iPSC gamma-delta T cells and to methods of use including treating diseases of interest.

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 collectively, the 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, which became effective on January 1, 2023, expanded the CCPA. The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal data, establishes restrictions on personal data retention, expands the types of data breaches that are subject to the CCPA's private right of action, and establishes 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, significant 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.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, 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. 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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. 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 until 2031, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% 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. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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.

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, 2022, we had 26 full-time employees, of whom 20 were primarily engaged in research and development activities. A total of eight 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:

- There is substantial doubt regarding our ability to continue as a going concern. We will require substantial additional funding to finance our operations, and if we are unable to raise capital, we could be forced to delay, reduce or explore other strategic options for certain of our development programs, or even terminate our operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.
- A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.
- The report of our independent registered public accounting firm for the years ended December 31, 2022 and 2021 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.
- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- Our ability to raise capital may be limited by applicable laws and regulations.
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are dependent on the successful clinical development, regulatory approval and commercialization of our gamma-delta T cell product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.
- Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our DeltEx product candidates utilize novel approaches to cell therapies, including cancer treatment, which presents significant challenges to successfully develop, manufacture and commercialize our product candidates.
- The clinical and commercial utility of our DeltEx platform is uncertain and may never be realized. Additionally, certain aspects of the function and production of gamma-delta T cells are poorly understood or currently unknown, and may only become known through further preclinical and clinical testing.
- Clinical product candidate development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Development of a product candidate intended for use in combination with an already approved therapy may present increased complexity and more or different challenges than development of a product candidate for use as a single agent or monotherapy.
- Public opinion and scrutiny of 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.
- 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.
- We may rely on third-party contractors or contract development manufacturing organization for the manufacturing of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.
- We currently store our gamma-delta T cells and biologic correlative and research specimens from clinical trials and development programs and clinical lentivectors at our research and development facilities and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise would cause delays in replacement, and our business could suffer.
- We are currently dependent on a single third-party supplier for manufacture of our automated manufacturing device and our lentiviral vectors. These are critical products required for the manufacturing of our product candidates, including INB-100, INB-200 and INB-400. Any damage or loss to the ability of our suppliers to deliver supplies in a timely manner could cause delays in manufacturing, or our clinical trials and our business could suffer.
- We rely on third-party healthcare professionals to administer gamma-delta T cells to patients, and our business could be harmed if these third parties administer these cells incorrectly.
- Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our license agreements with the University of Alabama at Birmingham Research Foundation, Children's Healthcare of Atlanta, Inc. and Emory University, or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- Our ability to compete in the pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on the services of our co-founders, William Ho, our President and Chief Executive Officer, and Dr. Lawrence Lamb, our Chief Scientific Officer, and the loss of these members of our management team or other key employees could impede, delay or prevent the successful development of our product pipeline, the completion of our current and planned clinical trials, and the commercialization of our products or in-licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan.
- 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.
- Unstable market and economic conditions, including as a result of recent bank closures, public health crises or geopolitical tensions, such as the Russia-Ukraine war, may have serious adverse consequences on our business, financial condition and share price.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions could adversely affect our current financial condition and projected business operations.

Risks Related to Our Financial Position and Capital Needs

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

Based on our current business strategy, there is substantial doubt concerning our ability to continue as a going concern. As of December 31, 2022, we had $18.2 million in cash, which will not allow us to fund our operations past mid-July of 2023, which includes reserves for all necessary winddown expenses. Based on our current business strategy, there is substantial doubt concerning our ability to continue as a going concern. We have taken measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including debt or equity financings or other arrangements.

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

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

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

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

Until such time, if ever, as we can generate substantial product revenue, we will need to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital, if available, through the sale of equity or convertible debt securities, 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 explore other strategic options for our product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. 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.

The report of our independent registered public accounting firm for the years ended December 31, 2022 and 2021 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Due to the uncertainty of our ability to meet our current operating and capital expenses, in its report on our audited annual financial statements as of and for the years ended December 31, 2022, our independent auditors included an explanatory paragraph regarding our ability to continue as going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations.

We 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 $28.5 million and $14.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $61.2 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. To date, we have never obtained regulatory approval for, or commercialized, any product candidates. It could be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

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

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, establishing and validating commercial-scale current good manufacturing practices, 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.

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

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

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

We are an early clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to financing and staffing our company, developing our technology, identifying and developing our product candidates, undertaking preclinical studies, initiating and conducting clinical trials for INB-200, INB-100 and INB-400, business planning and raising capital. Other than INB-200, INB-100 and INB-400, 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, multi-center pivotal clinical trials, obtain marketing approval, manufacture a clinical or commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to 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, INB-100, and INB-400, in our ongoing 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, INB-100 and INB-400, in ongoing clinical trials. Our 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-100, INB-200 and INB-400 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 undertaken 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, INB-200 and INB-400 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, which we are currently developing for the treatment of certain solid tumors, into the clinic. The manufacture of our cell therapies involves complex processes, including, for INB-100, where blood cells are isolated from an allogeneic donor via leukapheresis, gamma-delta T cells are expanded and activated, and other cells are removed through magnetic separation and then cryopreserved. For INB-200, blood cells are isolated from the patient via leukapheresis, the gamma-delta T cells are transduced, expanded and activated, and, if required, other cells are removed through magnetic separation prior to cryopreservation.

Any delay or difficulties in manufacturing lentiviral vector and/or clinical supply of INB-200, INB-100, INB-400 or any of our other current or future product candidates would adversely affect our business and operations. For additional details surrounding risks related to our manufacturing 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. While mismatched gamma-delta T cells are not known to initiate GvHD, we have observed grade 1 and/or 2 GvHD in all patients treated with INB-100 to date. 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 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 with uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.

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

A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our ongoing Phase 1 trials for INB-200, INB-100 and INB-400 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 a future public health crisis, 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 public health crises;
- the risk that enrolled subjects will drop out, develop complications or die before completion of the trial;
- the ability to develop and provide appropriate screening, product characterization and release assays;
- patients failing to complete a clinical trial or returning for post-treatment follow-up;
- our ability to manufacture the requisite materials for a patient and clinical trial; and
- inability of clinical sites to enroll patients as health care capacities are required to cope with natural disasters, epidemics or other health system emergencies.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on clinical research organizations, 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, SAEs, undesirable or potentially fatal side effects, cytokine release syndrome, viral or bacterial infections, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or

undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Should we observe SAEs in our clinical trials or identify undesirable side effects or other unexpected findings, our trials could be delayed or even terminated, and our development programs may be halted entirely.

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

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

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

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

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

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

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 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, or that of competitor's products and/or programs 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, INB-300 and INB-400, 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 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. For example, in September 2022, we announced a partnership with the Dunbar CAR-T Cell Program at the University of Louisville as the manufacturing center for our INB-400 clinical program. The facilities used by our partners and contract manufacturers must be submitted and disclosed to the FDA or other foreign regulatory agencies and may be selected for inspection or audit following the submission of an application to the FDA or other foreign regulatory agencies. To the extent that we engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with confidentiality agreements and the cGMP requirements for the manufacture of our product candidates. We have not yet had any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that meet specifications are capable or safe and effective. If such contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of third parties to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not agree that these facilities for the manufacture of our product candidates are acceptable or if it withdraws any such approval or acceptance in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

Our gamma-delta T cell products for INB-100, INB-200 and INB-400 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 33 patients and an additional large manufacturing run is currently expected to be completed in the first half of 2023. 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 public health crises, that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including 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.

For example, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities. The FDA has since 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 the past. If a prolonged government shutdown occurs, or if global health concerns 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, INB-400/INB-410 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-100, INB-200, INB-300, INB-400 and INB-410. 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 financial statements contained elsewhere in this Annual Report.

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

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

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

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. As of December 31, 2022, we owned, co-owned or exclusively licensed three issued U.S. patents, five issued European patents, six other issued foreign patents, eight pending U.S. applications, one pending PCT application and 45 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-100, INB-200 and INB-400, 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

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

We are highly dependent on our co-founders, 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, 2022, we had 26 full-time employees. As the clinical development of our product candidates progresses, we expect to need to hire employees and expand the scope of our operations, particularly in the areas of research, drug development, manufacturing, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any expansion of our operations may lead to significant 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. 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 deductibility of these carryforwards is limited. Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities.

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, 2022.

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

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

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

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

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

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

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We obtained product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If we determine that it is prudent to

increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Commercialization and Regulatory Compliance

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

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

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

If we fail to comply with applicable regulatory requirements following approval of our product candidates, a regulatory authority may, among other things, issue warning letters or untitled letters, mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products, require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance, seek an injunction or impose administrative, civil or criminal penalties or monetary fines, suspend or modify any ongoing clinical trials, or suspend, modify withdraw regulatory approval or restrict the marketing or manufacturing of the product candidate.

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

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

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

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

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

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

- the cost, efficacy, safety profile, convenience, ease of administration and other potential advantages compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of our relationships with patient communities;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product candidate together with other medications.

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

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

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

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for our product candidates in the European Union from the European Commission following the opinion of the European Medicines Agency, 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 the Russia-Ukraine war, natural disasters including earthquakes, typhoons, floods and fires, and public health emergencies.

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

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

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws 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 us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation

or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

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

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

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. 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 until 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% 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. More recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which included a number of significant drug pricing reforms, including extending enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs and Part D beneficiaries' annual out-of-pocket spending will be capped at $2,000 beginning in 2025.

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, the U.S. Department of Health and Human Services, or 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. Further, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. The Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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. 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

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

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

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

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

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

- commentary by investors on the prospects for our business or our common stock on the internet, including blogs, articles and message board, and/or social media and resulting in trading of our common stock;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- stock price and volume fluctuations attributable to inconsistent trading volume levels and a wide bid-ask in our common stock;
- announcement or expectation of additional financing efforts or sales by our stockholders;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of recent bank closures, public health crises or geographical tensions and wars, such as the Russia-Ukraine war; and
- investors' general perception of us and our business.

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

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

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, 2022, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock will, in the aggregate, beneficially own shares representing 64% 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.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- provide that our directors may be removed for cause only upon the vote of at least 66 2⁄3% of our outstanding shares of voting stock;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock; and
- require the approval of the holders of at least 66 2⁄3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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

Unstable market and economic conditions, including as a result of recent bank closures, public health crises or geopolitical tensions such as the Russia-Ukraine war, 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 macroeconomic uncertainty and volatile business environment have resulted in ongoing inflation, volatility in the capital markets, significantly reduced liquidity and credit availability, decreases in consumer demand and confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be materially or adversely impacted by if these unpredictable and unstable market conditions continue. Additionally, the Russia-Ukraine war 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, manufacturing 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 inflation expectations, recent bank closures, the changing interest rate environment, political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions could adversely affect our current financial condition and projected business operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, the Federal Deposit Insurance Corporation ("FDIC") took control and was appointed receiver of Silicon Valley Bank. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although the FDIC announced that all deposits with these banks would be fully insured, there continues to be uncertainty in the markets regarding the stability of regional banks and the safety of deposits in excess of the FDIC insured deposit limits. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash may be threatened. We have diversified our cash between several banking institutions in an attempt to minimize exposure. However, the FDIC only insures accounts in amounts up to $250,000 per depositor per insured bank. We currently have cash deposited in certain financial institutions significantly in excess of FDIC insured levels. If any of the banking institutions in which we have deposited funds ultimately fails, we may lose our deposits over $250,000. The loss of our deposits may have a material adverse effect on our business and financial condition. The ultimate outcome of these events cannot be predicted, but these events could have a material adverse effect on our business.

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 continue to incur increased costs as a result of operating as a public company, and our management will continue to 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 continue to 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.

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, 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 until the end of the fiscal year following the fifth anniversary of our initial public offering, or IPO. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404.

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

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

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

Item 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 are also leasing 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 28, 2026 and has an option for a five-year extension. We developed 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 that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

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 29, 2023, there were approximately 37 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 Initial Public Offering of Common Stock

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 our 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 us in connection with the IPO were paid directly or indirectly to (i) any of our officers, directors or associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our 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 used $23.7 million of the proceeds from the IPO.

Issuer Purchases of Equity Securities

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 product candidates for solid and liquid tumors. Gamma-delta T cells are a specialized population of T cells that possess unique properties. They are naturally occurring immune cells that 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, iPSC and genetically modified cell therapy approaches that are designed to effectively identify and eradicate tumor cells. We are the most clinically advanced gamma-delta T cell focused cellular therapy company and are utilizing our suite of DeltEx platform technologies as we aspire to eliminate cancer cells to achieve our mission of what we refer to as Cancer Zero─the elimination of all cancer cells in every patient battling the disease. We believe this lofty aspiration will one day be achievable, and that it's our responsibility to directly contribute to related global health efforts by pursuing scientific research that will advance cancer treatment.

Pursuant to a company-sponsored investigational new drug application, or IND, cleared by the FDA in late 2022, we plan to initiate a Phase 2 clinical trial of our lead product candidate, INB-400, for the treatment of newly diagnosed GBM, in the second half of 2023. This trial will expand the assessment of autologous, genetically modified gamma-delta T cells in newly diagnosed GBM patients across multiple centers across the country. We expect this will confirm the efficacy signal suggested by the investigator initiated trial INB-200. We are also seeking to complete two on-going Phase 1 clinical trials: INB-200, for the treatment of newly diagnosed GBM and INB-100 for the treatment of patients with high-risk hematologic malignancies that are undergoing allogenic hematopoietic stem cell transplantation, or HSCT. For INB-200, we expect to complete enrollment of Cohort 3 with clinical updates expected throughout 2023 and long-term follow-up in 2024. For INB-100, we expect to complete enrollment of the Phase 1 clinical trial and determine the RP2D in 2023, with updated results throughout 2023 and topline results in 2024. In addition, in the second half of 2023 we plan to submit an IND to initiate our Phase 1b clinical trial of INB-410 in which allogeneic genetically modified gamma-delta T cells will be assessed in both relapsed and newly diagnosed GBM patients.

We also have a portfolio of preclinical programs in development, including INB-300, which focuses on addressing various solid and liquid tumors using a dedicated gamma-delta nsCAR construct. We expect to present additional preclinical data demonstrating our proof-of-concept and the ability for a nsCAR construct to distinguish between tumors and healthy tissue the AACR annual meeting in 2023.

In May 2022, we unveiled the expansion of our DeltEx platform capabilities to include iPSC derived gamma-delta T cells. iPSCs represent a significant step toward next generation approaches of cellular manufacturing for true allogeneic and potentially 'off-the-shelf' innate cell therapies. We intend to continue to advance our internal research, including the application of our proprietary DeltEx technologies into additional solid tumor indications, which we expect to announce in the first half of 2023. We plan to file several company-sponsored IND applications for our pipeline product candidates over the next few years.

In August 2022, we completed an underwritten public offering of 5,663,686 shares of common stock at a price to the public of $1.90 per share, resulting in net proceeds of $9.4 million, after deducting underwriting discounts, commissions and offering expenses.

In November 2022, we filed a shelf registration statement on Form S-3 (File No. 333-268288), or the Shelf Registration Statement, with the Securities and Exchange Commission, or SEC, which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $200 million of our securities, of which $50 million of common stock may be issued and sold pursuant to an at-the-market offering, or ATM, program. We entered into a Controlled Equity Offering℠ sales agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, and Truist Securities, Inc., or Truist, under which Cantor Fitzgerald and Truist agreed to act as our sales agents to sell shares of our common stock, from time to time, through the ATM program. For additional information, see "—Liquidity" below.

Since inception in 2016, our operations have focused on identifying and developing potential product candidates, conducting clinical trials, organizing and staffing, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations primarily through the sale of equity and equity-linked securities. Through December 31, 2022, we raised an aggregate of $86.5 million of gross proceeds from the sale of our securities, including through our IPO, August 2022 follow-on offering and November 2022 ATM transaction utilization.

Going Concern

We have not yet generated product sales and as a result have experienced operating losses since inception. We expect to incur additional losses in the 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 costs associated with operating as a public company, and, based on our business strategy, our existing cash of $18.2 million as of December 31, 2022 will not be sufficient to fund the projected operating expenses and capital expenditure requirements past mid-July of 2023, which includes reserves for all necessary winddown expenses. Accordingly, there is substantial doubt about our ability to continue as a going concern.

We have taken measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy, including our ability to achieve the anticipated milestones for our preclinical and clinical programs. To continue to fund our operations, management has developed plans, which primarily consist of raising additional capital through some combination of equity and/or debt offerings, including through our ATM program, and identifying strategic collaborations, licensing or other arrangements to support development of our product candidates. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed, that management will be able to obtain financing or enter into a collaboration on terms acceptable to us, or that any additional financing or revenue generated through third-party collaborations will be sufficient to fund our operations. If additional capital is not available to us on a timely basis, or at all, we will be required to take additional actions beyond the cost preservation measures initiated to address our liquidity needs, including to explore other strategic options, continue to further reduce operating expense or to delay, reduce the scope of, discontinue or alter our research and development activities.

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

Components of Our Results of Operations

Revenue

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

Operating Expenses

Research and Development Expenses

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

- employee-related expenses, including salaries, related-benefits 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. We allocate our direct external research and development costs across each product candidate. Preclinical expenses consist of external research and development costs associated with activities to support our current and future clinical programs, but are not allocated by product candidate due to the overlap of the potential benefit of those efforts across multiple product candidates.

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; 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, 2022 and 2021

The following table sets forth our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 14,062	$ 7,347	$ 6,715
General and administrative	14,459	7,306	7,153
Total operating expenses	28,521	14,653	13,868
Loss from operations	(28,521)	(14,653)	13,868
Net loss	$ (28,521)	$ (14,653)	$ 13,868

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Direct research and development expenses:			
INB-100	$ 266	$ 180	$ 86
INB-200	842	837	5
INB-400	4,378	—	4,378
Unallocated expenses			
Preclinical	118	1,637	(1,519)
Personnel expenses (including stock-based compensation)	5,871	3,407	2,464
Facility-related and other	2,587	1,371	1,216
R&D credit income	—	(85)	85
Total research and development expenses	$ 14,062	$ 7,347	$ 6,715

Research and development expenses were $14.1 million for the year ended December 31, 2022, compared to $7.3 million for the comparable prior year period, an increase of $6.7 million. Third-party clinical trial-related activities and contract manufacturing costs for the ongoing INB-400 clinical trial accounted for $4.3 million of the increase. Personnel-related costs, including salaries, benefits and stock-based compensation increased $2.5 million as a result of the increase our headcount. Facility related and other costs increased $1.2 million due primarily to general increases in research and development activities in connection with program development and higher allocations due to the increase in headcount over the prior year, which was partially offset by a decrease in preclinical costs related to INB-300 and INB-500.

General and Administrative Expenses

General and administrative expenses were $14.5 million for the year ended December 31, 2022, compared to $7.3 million for the comparable prior year period. The increase of $7.2 million was primarily due to increases in professional services, facility related and other costs, and personnel expenses. Professional services increased $2.6 million due to higher utilization of consultants, as well as increases in audit, accounting and legal service fees as a result of our ongoing public company obligations. Facility-related and other costs increased $2.6 million, primarily due to higher insurance costs related to being a public company and other general expenses in support of our increased headcount. Personnel costs increased $2.0 million due to the increased headcount and stock-based compensation expense.

Liquidity and Capital Resources

Overview

As of December 31, 2022, we had cash of $18.2 million. To date, we have funded our operations primarily with proceeds from various public and private offerings of our common and preferred stock, including through our follow-on offering completed in August 2022 and through the ATM transactions completed in 2022. Through December 31, 2022, we have raised an aggregate of $86.5 million of gross proceeds from the sale of our securities. Our plan of operation is to continue implementing our business strategy, continue research and development of INB-100, INB-200, INB-400 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. Without additional capital, we do not expect our cash will be sufficient to fund our projected operating requirements or allow us to fund our operating plan past mid-July 2023, which includes reserves for all necessary winddown expenses.

Going Concern

Our financial statements for the year ended December 31, 2022 have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company on a going concern basis. The going concern basis assumes that assets are realized, and liabilities are extinguished in the ordinary course of business at amounts disclosed in the financial statements. We have not yet generated product sales and as a result have experienced operating losses since inception. We expect to incur additional losses in the 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 costs associated with operating as a public company, and, based on our business strategy, our existing cash of $18.2 million as of December 31, 2022 will not be sufficient to fund the projected operating expenses and capital expenditure requirements past mid-July of 2023, which includes reserves for all necessary winddown expenses. Accordingly, the report from our independent registered public accounting firm for the year ended December 31, 2022 includes an explanatory paragraph stating that our recurring losses since inception raises substantial doubt about our ability to continue as a going concern. Our existing cash will not allow us to fund our operations past mid-July of 2023, which includes reserves for all necessary winddown expenses. We have taken measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy, including our ability to achieve the anticipated milestones for our preclinical and clinical programs.

To continue to fund our operations, management has developed plans, which primarily consist of raising additional capital through some combination of equity and/or debt offerings, including through our ATM program, and identifying strategic collaborations, licensing or other arrangements to support development of our product candidates. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available, when needed, that management will be able to obtain financing or enter into a collaboration on terms acceptable to us, or that any additional financing or revenue generated through third-party collaborations will be sufficient to fund our operations for at least 12 months from the issuance of the financial statements. If additional capital is not available to us on a timely basis, or at all, we will be required to take additional actions beyond the cost preservation measures initiated to address our liquidity needs, including to explore other strategic options continue to further reduce operating expense or to delay, reduce the scope of, discontinue or alter our research and development activities.

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

Funding 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 public health crises, and geopolitical tensions, such as Russia-Ukraine war;
- 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.

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

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

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

If we raise funds through strategic collaboration, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions, 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 recent bank failures, the COVID-19 pandemic and other geopolitical tensions, such as the Russia-Ukraine war. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or explore other strategic options for our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Material Cash Requirements

Our material cash requirements as of December 31, 2022 included operating lease commitments, including the lease of our current headquarters office in New York, New York, laboratory space in Birmingham, Alabama and a manufacturing service agreement with a third party to engage in research of cell therapy products. As of December 31, 2022, we had fixed lease payment obligations of $7.5 million, with $2.0 million payable within 12 months. Refer to Note 14 to our financial statements for additional information.

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

At-the-Market Offering Program

In November 2022, we filed the Shelf Registration Statement with the SEC, which permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $200 million of our securities, of which $50 million of common stock may be issued and sold pursuant to the ATM program. We entered into the Sales Agreement with Cantor Fitzgerald and Truist, under which Cantor Fitzgerald and Truist agreed to act as our sales agents to sell shares of our common stock, from time to time, through the ATM program. As of December 31, 2022, our calculated public float was less than $75.0 million. Under current SEC regulations, if at any time our public float is less than $75.0 million, and for so long as our public float remains less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the "baby shelf" limitations. As of March 29, 2023, we have sold an aggregate of 435,901 shares of common stock pursuant to the ATM program, resulting in net proceeds of approximately $0.8 million, after deducting underwriting discounts.

Cash Flows

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

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (24,121)	$ (13,509)
Net cash used in investing activities	(3,705)	(309)
Net cash provided by financing activities	8,988	32,955
Net (decrease) increase in cash	$ (18,838)	$ 19,137

Operating Activities

Cash used in operating activities was $24.1 million during the year ended December 31, 2022, primarily due to our net loss of $28.5 million, partially offset by an increase in our non-cash charges of $4.6 million. Increases in our non-cash charges consisted primarily of $3.5 million in stock-based compensation due to increased employee headcount resulting from growth in our business and $1.0 million in amortization of operating and finance leases.

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.

Investing Activities

Cash used in investing activities was $3.7 million during the year ended December 31, 2022, primarily due to completion of the space buildout located in Alabama in the current year.

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 $9.0 million during the year ended December 31, 2022, primarily due to $9.4 million in proceeds received from the sale of common stock in our follow-on offering completed in August 2022, $0.1 million in proceeds received from our ATM program and $0.1 million from exercise of common stock options, slightly offset by $0.6 million in principal payments of financing leases.

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.

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

We have listed below our critical accounting 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.

Critical Accounting Policies

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

Research and Development Costs

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

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each 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 company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as allowed by the SEC Staff Accounting Bulletin, 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.

Recent Accounting Pronouncements

We did not adopt any new accounting guidance during the year ended December 31, 2022 that had a material impact on the financial statements or disclosures. Additionally, there is no pending accounting guidance that we expect to have a material impact on the financial statements.

Emerging Growth Company and Smaller Reporting Company Status

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

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

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

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates was less than $700 million at the closing of our IPO and our annual revenue for 2021 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 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, 2022 and 2021, 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, 2022 and 2021 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.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses from operations that raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 30, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash	$ 18,182	$ 37,021
Prepaid expenses and other current assets	4,052	1,959
Total Current Assets	22,234	38,980
Non-current assets		
Property and equipment, net	4,397	97
Construction in progress	29	403
Restricted cash	252	251
Right of use assets - financing leases	1,691	704
Right of use assets - operating leases	4,181	1,630
Other non-current assets	255	158
Total Non-Current Assets	10,805	3,243
Total Assets	$ 33,039	$ 42,223
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	$ 2,091	$ 395
Accrued expenses and other current liabilities	2,342	1,235
Short-term financing lease liability	682	392
Short-term operating lease liability	707	234
Total Current Liabilities	5,822	2,256
Long-term financing lease liability	811	269
Long-term operating lease liability	3,674	1,515
Total Non-Current Liabilities	4,485	1,784
Total Liabilities	10,307	4,040
Stockholders' Equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized at December 31, 2022 and 2021, respectively. No shares issued and outstanding	—	—
Common stock, par value $0.0001 per share; 490,000,000 shares authorized at December 31, 2022 and 2021; 24,545,157 and 18,781,242 shares issued and outstanding at December 31, 2022 and 2021, respectively	3	2
Additional paid-in capital	83,941	70,872
Accumulated deficit	(61,212)	(32,691)
Total Stockholders' Equity	22,732	38,183
Total Liabilities and Stockholders' Equity	$ 33,039	$ 42,223

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

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 14,062	$ 7,347
General and administrative	14,459	7,306
Total operating expenses	28,521	14,653
Loss from operations	(28,521)	(14,653)
Net loss	$ (28,521)	$ (14,653)
Net loss per share – basic and diluted	$ (1.36)	$ (1.47)
Weighted-average number of shares used in computing net loss per common share – basic and diluted	20,967,955	9,969,733

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
	Shares	Amount	Shares	Amount			
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
Issuance of common stock, net of issuance costs of $919	—	—	5,706,686	1	9,541	—	9,542
Stock options exercises	—	—	57,229	—	61	—	61
Stock-based compensation expense	—	—	—	—	3,467	—	3,467
Net loss	—	—	—	—	—	(28,521)	(28,521)
Balance at December 31, 2022	—	—	24,545,157	$ 3	$ 83,941	$ (61,212)	$ 22,732

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

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

	Year Ended December 31,	
	2022	2021
Operating activities		
Net loss	$ (28,521)	$ (14,653)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	89
Non-cash stock-based compensation	3,467	2,195
Amortization of financing lease right-of-use assets	461	537
Amortization of operating lease right-of-use assets	495	162
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,093)	(1,876)
Other non-current assets	(97)	(159)
Accounts payable	1,510	(319)
Accrued expenses and other current liabilities	924	554
Short-term operating lease liabilities	112	158
Long-term operating lease liabilities	(526)	(197)
Net cash used in operating activities	(24,121)	(13,509)
Investing activities		
Purchases of property and equipment	(3,689)	—
Construction in progress	(16)	(309)
Net cash used in investing activities	(3,705)	(309)
Financing activities		
Proceeds from exercise of common stock options	61	30
Proceeds from the issuance of common stock, net of issuance costs	9,542	36,327
Principal payments on financing leases	(615)	(535)
Repayment of loan payable	—	(174)
Payment of deferred offering costs	—	(2,693)
Net cash provided by financing activities	8,988	32,955
Net (decrease) increase in cash and restricted cash	(18,838)	19,137
Cash and restricted cash at beginning of year	37,272	18,135
Cash and restricted cash at end of year	$ 18,434	$ 37,272
Supplemental disclosure of non-cash operating, financing and investing information:		
Construction in progress included in accounts payable	$ 13	$ 94
Property and equipment in accounts payable	$ 356	$ —
Transfer of construction in progress to property and equipment	$ 403	$ —
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 financing lease right-of-use assets	$ 1,448	$ —
Initial measurement of operating lease right-of-use assets	$ 3,046	$ 1,693
Initial measurement of lease liabilities	$ 4,286	$ 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:

	December 31, 2022	December 31, 2021
Cash, end of year	$ 18,182	$ 37,021
Long-term restricted cash, end of year	252	251
Cash and restricted cash, end of year	$ 18,434	$ 37,272

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

IN8BIO, INC.
Notes to 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 product candidates for solid and liquid tumors. 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 hematologic malignancies that are undergoing hematopoietic stem cell transplantation ("HSCT"). In addition, the Company is currently preparing to initiate patient enrollment in the company-sponsored Phase 2 clinical trial of INB-400 in which autologous genetically modified gamma-delta T cells will be assessed in newly diagnosed GBM patients. With additional funding, the Company is expecting to submit its company-sponsored investigational new drug application and initiate its Phase 1b clinical trial of INB-410 in which allogeneic genetically modified gamma-delta T cells will be assessed in both relapsed and newly diagnosed GBM patients in late 2023. Additionally, the Company's DeltEx platform has yielded a broad portfolio of preclinical programs, including INB-300 and INB-500, focused on addressing GBM and 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 does not have any subsidiaries to consolidate. The Company is headquartered in New York, New York.

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).

Going Concern

To date, the Company has funded its operations primarily with proceeds from various public and private offerings of its common and preferred stock. The Company has incurred recurring losses and negative operating cash flows since its inception, including net losses of $28.5 million and $14.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company had an accumulated deficit of $61.2 million.

On August 16, 2022, the Company completed an underwritten public offering of 5,394,737 shares of its common stock at a public offering price of $1.90 per share, for net proceeds of approximately $9.0 million, after deducting underwriting discounts, commissions and offering expenses. On August 19, 2022, the underwriter partially exercised their option to purchase an additional 268,949 shares at the public offering price of $1.90 per share, resulting in additional net proceeds of approximately $0.4 million, after deducting underwriting discounts, commissions and offering expenses, increasing the aggregate net proceeds from the offering to approximately $9.4 million.

In November 2022, the Company filed a shelf registration statement on Form S-3 (File No. 333-268288) (the "Shelf Registration Statement") with the Securities and Exchange Commission ("SEC"), which permits the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $200 million of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, of which $50 million of common stock may be issued and sold pursuant to an at-the-market offering program ("ATM"). The Company entered into a Controlled Equity Offering^{SM} sales agreement, or the Sales Agreement, with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") and Truist Securities, Inc. ("Truist") under which Cantor Fitzgerald and Truist agreed to act as sales agents to sell shares of the Company's common stock, from time to time, through the ATM program. Under current SEC regulations, if at any time the Company's public float is less than $75.0 million, and for so long as the Company's public float remains less than $75.0 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float, which is referred to as the baby shelf rules. As of December 31, 2022, the Company's calculated public float was less than $75.0 million. During the year ended December 31, 2022, the Company sold an aggregate of 43,000 shares of common stock under the ATM, resulting in net proceeds of approximately $0.1 million, after deducting underwriting discounts.

The Company has not yet generated product sales and as a result has experienced operating losses since inception. The Company expects to incur additional losses in the future as it advances its product candidates through clinical trials, seeks to expand its product candidate portfolio through developing additional product candidates, grows its clinical, regulatory and quality capabilities, and incurs costs associated with operating as a public company, and, based on the Company's business strategy, its existing cash of $18.2 million as of December 31, 2022 will not be sufficient to fund the Company's projected operating expenses and capital expenditure requirements beyond mid-July of 2023, which includes reserves for all necessary winddown expenses. Accordingly, there is substantial doubt about the Company's ability to continue to operate as a going concern. To continue to fund the operations of the Company beyond this time period, management has developed plans, which primarily consist of raising additional capital through some combination of public equity offerings, including through ATM offerings, and identifying strategic collaborations, licensing or other arrangements to support development of the Company's product candidates. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed, that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company, or that any additional financing or revenue generated through third party collaborations will be sufficient to fund our operations through this time period. If additional capital is not available, the Company will have to significantly delay, scale back or discontinue research and development programs or future commercialization efforts. The actual amount of cash that the Company will need to operate is subject to many factors. The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Concentration of Credit Risk

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

Property and Equipment

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

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

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or disposal of property and equipment, the cost and related accumulated depreciation and amortization are removed from the 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, 2022 and 2021.

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 million was recognized as a reduction to prepaid expenses and other current assets and $0.02 million 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.

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 in 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 operations. As of December 31, 2022, 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 has resulted or will result in a material tax benefit to the Company.

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 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 the 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.

Recent Accounting Pronouncements

The Company did not adopt any new accounting guidance during the year ended December 31, 2022 that had a material impact on the financial statements or disclosures. Additionally, there is no pending accounting guidance that the Company expects to have a material impact on the financial statements.

3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	December 31, 2022	December 31, 2021
Prepaid research and development	$ 2,562	$ 49
Prepaid insurance	1,258	1,858
Other	232	52
Prepaid expenses and other current assets	$ 4,052	$ 1,959

4. PROPERTY AND EQUIPMENT, NET

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

	December 31, 2022	December 31, 2021
Machinery and equipment	$ 358	$ 443
Furniture and fixtures	335	—
Software	126	—
Leasehold improvements	3,899	—
Less accumulated depreciation and amortization	(321)	(346)
Property and equipment, net	$ 4,397	$ 97

Depreciation and amortization expense was $0.1 million for each of the years ended December 31, 2022 and 2021.

5. CONSTRUCTION IN PROGRESS

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

	December 31, 2022	December 31, 2021
Furniture	$ 29	$ 77
Leasehold improvements	—	200
Internal use software not yet in service	—	126
Construction in progress	$ 29	$ 403

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31, 2022	December 31, 2021
Accrued clinical trials	$ 253	$ 196
Accrued compensation	1,460	926
Accrued legal	211	62
Accrued other	418	51
Total accrued expenses and other current liabilities	$ 2,342	$ 1,235

7. 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, matured on April 16, 2022 and bore interest at a rate of 1.0% per annum, payable monthly commencing on November 16, 2020.

Funds from the Loan could only be used for payroll costs, costs 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.

8. STOCKHOLDERS' EQUITY

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

In August 2021, upon the 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 shares of preferred stock outstanding as of December 31, 2022 and 2021.

Equity Offerings

In August 2022, the Company issued and sold 5,663,686 shares of common stock at a public offering price of $1.90 per share, resulting in net proceeds of $9.4 million, after deducting underwriting discounts, commissions and offering expenses.

ATM Facilities

In November 2022, the Company filed the Shelf Registration Statement with the SEC, which permits the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $200 million of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, of which $50 million of common stock may be issued and sold pursuant to the ATM. The Company entered into the Sales Agreement with Cantor Fitzgerald and Truist under which Cantor Fitzgerald and Truist agreed to act as sales agents to sell shares of the Company's common stock, from time to time, through an ATM pursuant to the effective Shelf Registration Statement. Under current SEC regulations, if at any time the Company's public float is less than $75.0 million, and for so long as the Company's public float remains less than $75.0 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float, which is referred to as the baby shelf rules. As of December 31, 2022, our calculated public float was less than $75.0 million.

During the year ended December 31, 2022, the Company sold an aggregate of 43,000 shares of common stock under the ATM resulting in net proceeds of approximately $0.1 million, after deducting underwriting discounts.

9. STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

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

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the "2020 Plan") was approved by the Board of Directors and the Company's stockholders and became effective on July 29, 2021. The Board of Directors, or a 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, (the "IRC") as amended, to employees, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to 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 automatically increases 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. On January 1, 2022, the shares reserved for issuance was increased to 5,139,062 shares. As of December 31, 2022, 979,502 shares were available for grant pursuant to the 2020 Plan.

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 automatically increases 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. On January 1, 2023, the shares reserved for issuance was increased to 633,264 shares. As of December 31, 2022, 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. 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, 2022:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	2,306,379	$ 6.51	8.99	$ 983
Granted	1,845,682	2.85		
Exercised	(57,229)	1.07		
Forfeited	(91,538)	6.47		
Outstanding at December 31, 2022	4,003,294	$ 4.90	8.28	$ 860
Exercisable at December 31, 2022	1,115,004	$ 6.16	7.89	$ 195
Options expected to vest as of December 31, 2022	2,888,290	$ 4.41	8.96	$ 664

The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $2.85 and $5.41, 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 December 31, 2022. The aggregate intrinsic value of stock options exercised in the year ended December 31, 2022 was $0.1 million.

Stock-Based Compensation Expense

For the years ended December 31, 2022 and 2021, 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, 2022	December 31, 2021
Volatility	86.91% - 89.16%	85.67% - 89.15%
Expected life (years)	5.27 - 6.08	5.49 - 6.68
Risk-free interest rate	1.99% - 4.31%	0.66% - 1.32%
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, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 1,404	$ 1,014
General and administrative	2,063	$ 1,181
Total stock-based compensation expense	$ 3,467	$ 2,195

No related tax benefits from stock-based compensation expense were recognized for the years ended December 31, 2022 and 2021. As of December 31, 2022, there was $8.3 million in unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 2.67 years.

10. LICENSE AGREEMENTS

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

In June 2016, the Company entered into an exclusive license agreement with 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 licensed product, or the expiration of the relevant licensed patents, whichever is later. The Company may terminate the Emory License Agreement at will at any time upon prior written notice to Emory University. Emory University has the right to terminate the Emory License Agreement if the Company materially breaches the agreement (including failure to meet diligence obligations) and fails to cure such breach within a specified cure period, if the Company becomes bankrupt or insolvent or decides to cease development and commercialization of the licensed product, or if the Company challenges the validity or enforceability of any licensed patents.

Exclusive License Agreement with UABRF

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

In consideration of the license granted under the UABRF License Agreement, the Company paid UABRF a nominal upfront payment and issued 91,250 shares of common stock to UABRF, which were subject to certain 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. This provision was fully satisfied as of August 2020, at which time the Company raised an aggregate of $36.6 million through the sale of their securities. Between March 2017 and August 2020, the Company issued UABRF an additional 151,382 shares of its common stock in satisfaction of this antidilution provision.

11. INCOME TAXES

For the years ended December 31, 2022 and 2021, the tax provision (benefit) consisted of (in thousands):

	December 31, 2022	December 31, 2021
Current provision (benefit):		
Federal	$ —	$ —
State	—	—
Total	—	—
Deferred provision (benefit)		
Federal	(5,967)	(2,670)
State	1,455	(1,938)
Total	(4,512)	(4,608)
Change in valuation allowance	4,512	4,608
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 the years ended December 31, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
U.S. Federal statutory rate	21%	21%
State taxes, net of federal benefit	0%	10%
Stock-based compensation	-1%	-2%
Other permanent differences	0%	-1%
True up adjustments	-4%	3%
Change in valuation allowance	-16%	-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, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Stock-based compensation	$ 920	$ 337
Net operating loss carryforwards and alternative minimum tax credits	9,737	6,803
Lease liabilities	1,234	791
Reserves and accruals	307	304
Intangibles and fixed assets	2,940	1,922
Total deferred tax assets	15,137	10,157
Deferred tax liabilities:		
ROU assets	(1,233)	(766)
Total deferred tax liabilities	(1,233)	(766)
Valuation allowance	(13,903)	(9,391)
Deferred tax assets (liabilities), net	$ —	$ —

The Tax Cuts and Jobs Act of 2017 (TCJA) amended IRC Section 174 to require capitalization of all research and developmental ("R&D") costs incurred in tax years beginning after December 31, 2021. These costs are required to be amortized over five years if the R&D activities are performed in the United States or over 15 years if the activities were performed outside the United States. The Company capitalized approximately $9.8 million of R&D expenses incurred during the year ended December 31, 2022.

As of December 31, 2022, the Company had federal net operating loss carryforwards of approximately $36.6 million, which do not expire. As of December 31, 2022, the Company had state net operating loss carryforwards of approximately $25.0 million which will begin to expire in 2039.

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, 2022 was an increase of $4.5 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 as of December 31 2022. Management concluded that the Company did not undergo an ownership change as defined under IRC Section 382(g); all the attributes disclosed in this footnote 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 remain open to examination due to the carryover of net operating losses or tax credits.

12. NET LOSS PER SHARE

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

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

	Year Ended December 31,	
	2022	2021
Net loss	$ (28,521)	$ (14,653)
Net loss per share—basic and diluted	$ (1.36)	$ (1.47)
Weighted-average number of shares used in computing net loss per share—basic and diluted	20,967,955	9,969,733

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,	
	2022	2021
Stock options to purchase common stock	3,200,412	1,723,587

13. COMMITMENTS AND CONTINGENCIES

Intellectual Property

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

Legal Proceedings

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

14. FACILITY LEASES

The Company has historically entered into lease arrangements for its facilities. As of December 31, 2022, 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 $2.5 million for equipment purchases in the form of sale and leasebacks or direct leases. As of December 31, 2022, 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 $255,000 and $141,000 as of December 31, 2022 and 2021, respectively, and are included in other non-current assets on the balance sheets.

Operating Leases

The Company has an operating lease for office space in Birmingham, Alabama, for a 63-month term ending in March 2026, with an option to extend five years. Throughout the term of the lease, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the lease, including a proportionate share of applicable taxes, operating expenses and utilities.

The Company has an operating lease for office space in New York, New York, with a term that commenced on September 15, 2021, and continues through March 2027. Throughout the term of the lease, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the lease, including a proportionate share of applicable taxes, operating expenses and utilities.

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

The Company had a build-to-suit lease agreement with a third party to build out the Company's labs in Birmingham, Alabama, which was substantially completed in December 2022. The agreement had a threshold of $4.0 million of total costs incurred. The costs incurred and classified as property and equipment, net on the balance sheets were $4.1 million as of December 31, 2022.

The operating leases require security deposits at the inception of each lease. The security deposits amounted to approximately $262,000 and $278,000 as of December 31, 2022 and 2021, respectively. As of December 31, 2022, approximately $252,000 was included in restricted cash and $10,000 was included in other current assets. As of December 31, 2021, approximately $251,000 was included in restricted cash, $10,000 was included in other current assets and $17,000 was included in other non-current assets.

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 years ended December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Lease Cost		
Amortization of finance right-of-use assets	$ 461	$ 537
Interest on finance lease liabilities	53	86
Operating lease cost	731	280
Short-term lease cost	—	460
Total lease cost	$ 1,245	$ 1,363

	December 31, 2022
Other Lease Information	
Cash paid for amounts included in the measurement of lease liability – finance leases	$ 261
Cash paid for amounts included in the measurement of lease liability – operating leases	$ 651
Weighted-average remaining lease term – finance leases	2.27 years
Weighted-average remaining lease term – operating leases	4.98 years
Weighted-average discount rate – finance leases	9.7%
Weighted-average discount rate – operating leases	12.1%

The following table reconciles the undiscounted cash flows to the operating and financing lease liabilities at December 31, 2022 (in thousands):

	Financing Leases	Operating Leases
2023	$ 789	$ 1,190
2024	566	1,212
2025	302	1,224
2026	—	1,013
2027	—	768
Thereafter	—	421
Total lease payment	1,657	5,828
Less: interest	164	1,447
Total lease liabilities	1,493	4,381
Less: short-term lease liability	682	707
Long-term lease liability	$ 811	$ 3,674

15. SUBSEQUENT EVENTS

Subsequent to December 31, 2022, the Company sold an aggregate of 392,901 shares of common stock under the ATM resulting in net proceeds of approximately $0.7 million, after deducting underwriting discounts.

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

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2022 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussion regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to the deferral allowed under the JOBS Act for emerging growth companies.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2022, the design of our

disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

In 2022, we implemented the first phase of our enterprise resource planning software, NetSuite, as part of a plan to integrate and upgrade our systems and processes. The implementation of this software is scheduled to continue in phases over a number of years as the Company grows and as we move towards commercialization. As the phased implementation of this system occurs, we expect certain changes to our processes and procedures which, in turn, will result in changes to our internal control over financial reporting. We expect NetSuite to continue to strengthen our internal financial controls. Management will continue to evaluate and monitor our internal controls as processes and procedures in each of the affected areas evolve. As we are still in the process of implementing these additional phases, no change in our internal control over financial reporting occurred during the quarter ended December 31, 2022.

Other than as discussed above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2022, 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

Certain information required by Part III is omitted from this report because we will file with the SEC a definitive proxy statement pursuant to Regulation 14A, or the 2023 Proxy Statement, no later than 120 days after the end of our fiscal year, and certain information included therein is incorporated herein by reference.

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," "Executive Officers," "Information Regarding the Board and Corporate Governance" and "Delinquent Section 16(a) Reports," if applicable, in our 2023 Proxy Statement.

Information regarding our Code of Business Conduct and Ethics, or the Code of Conduct, required by this item will be contained in our 2023 Proxy Statement under the caption "Information Regarding the Board and Corporate Governance – Code of Business Conduct and Ethics," and is hereby incorporated by reference. If we make any substantive amendments to the Code of Conduct or grants any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on its website. The full text of our Code of Conduct is available at the investors section of our website at *www.in8bio.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the section titled "Executive Officer and Director Compensation" in our 2023 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 2023 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 2023 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

Information regarding accounting fees and services required by this item will be contained in our 2023 Proxy Statement in Proposal 2 under the captions "–Independent Registered Public Accounting Firm Fees" and "–Pre-Approval Policies and Procedures" and is hereby incorporated by reference.

PART IV

Item 15. Exhibits 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 included in Item 8 of Part II hereof.

(a)(3) Exhibits

The exhibits required to be filed or furnished as part of this report are listed in the Exhibit List set forth below.

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 (incorporated herein by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K (File No. 001-39692), filed with the SEC on March 17, 2022).
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
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 (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K (File No. 001-39692), filed with the SEC on March 17, 2022)
10.20+	Employment Agreement between Registrant and Patrick McCall, dated January 20, 2021 (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K (File No. 001-39692), filed with the SEC on March 17, 2022).
10.21+	Employment Agreement between Registrant and Kate Rochlin, dated December 21, 2020.
23.1	Consent of Independent Registered Public 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 30, 2023 By: /s/ William Ho
William Ho
Chief Executive Officer
(Principal Executive Officer)

March 30, 2023 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 30, 2023
/s/ Patrick McCall **Patrick McCall**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 30, 2023
/s/ Alan S. Roemer **Alan S. Roemer**	Chairman of the Board of Directors	March 30, 2023
/s/ Peter Brandt **Peter Brandt**	Director	March 30, 2023
/s/ Emily Fairbairn **Emily Fairbairn**	Director	March 30, 2023
/s/ Luba Greenwood **Luba Greenwood**	Director	March 30, 2023
/s/ Travis Whitfill **Travis Whitfill**	Director	March 30, 2023

EXECUTIVE OFFICERS

William Ho
President, Chief Executive Officer and Co-Founder

Trishna Goswami, M.D.
Chief Medical Officer

Lawrence Lamb, Ph.D.
Executive Vice President, Chief Scientific Officer and Co-Founder

Patrick McCall
Chief Financial Officer and Corporate Secretary

Kate Rochlin, Ph.D.
Chief Operating Officer

BOARD OF DIRECTORS

Alan S. Roemer
Independent Biotechnology Advisor

Peter Brandt
Former Chair of the Board
Rexahn Pharmaceuticals, Inc.

Emily Wang Fairbairn
Co-Founder and Former Chief Executive Officer
Ascend Capital

Jeremy Graff
Chief Scientific Officer
IMV, Inc.

Luba Greenwood
Chief Executive Officer, Kojin Therapeutics, Inc.
Managing Partner, Binney Street Capital, LLC

William Ho
President, Chief Executive Officer and Co-Founder
IN8bio, Inc.

Travis Whitfill
Partner
Bios Equity Partners, LP

LISTING

Our common stock is listed on Nasdaq under the ticker symbols “INAB.”

TRANSFER AGENT AND REGISTRAR

Computershare Investor Services
462 South 4th Street, Suite 1600
Louisville, KY 40202
www.computershare.com
webqueries@computershare.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

CohnReznick LLP

LEGAL COUNSEL

Cooley LLP

ANNUAL MEETING

June 15, 2023, at 9:00 a.m. Eastern time
Virtual Meeting Only: **www.proxydocs.com/INAB**

FORM 10-K

A copy of our Form 10-K filed with the Securities and Exchange Commission (SEC) will be made available to all stockholders at no charge.

The Form 10-K also can be accessed through the SEC website at **www.sec.gov**, or through our Investor website at **investors.in8bio.com**.

To receive a copy by mail please contact:

Investor Relations
IN8Bio, Inc.
350 5th Avenue, Suite 5330
New York, NY 10118
info@in8bio.com