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

# FORM 10-K

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

For the fiscal year ended: **December 31, 2018**

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-38793**

# INMUNE BIO INC.

(Exact name of registrant as specified in its charter)

| **Nevada** | **47-5205835** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**INMUNE BIO INC.**
**David Moss**
**1224 Prospect Street, Suite 150**
**La Jolla, CA 92037**
**Phone: (858) 964 3720**
(Address of principal executive offices)(Zip Code)

**(858) 964 3720**
(Registrant's telephone number, including area code)

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

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

| **Title of each class** | **Name of Market Where Traded** |
|---|---|
| Common Stock ($.001 par value) | Nasdaq |

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 Section 15(d) of the Act. Yes ☐ No ☒

Indicate by checkmark 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 ☒

Explanatory Note: The Company did not become subject to the filing requirements of the Securities Exchange Act of 1934, as amended until February 1, 2019.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☒ |
| Emerging Growth Company | ☒ | | |

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

As of December 31, 2018, the last business day of the registrant's most recently completed second quarter, there was no public market for the registrant's common stock. The registrant's common stock began trading on the Nasdaq on February 4, 2019.

As of March 25, 2019, there are 9,740,261 shares of common stock, $0.001 par value per share outstanding.

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## PART I

*All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "INmune Bio" the "Company," "we," "us," and "our" refer to INmune Bio, Inc., a Nevada corporation.*

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains "forward-looking statements" Forward-looking statements reflect our current view about future events. When used in this Report, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements, include, but are not limited to, statements contained in this Report relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward–looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, our ability to raise capital to fund continuing operations; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize products and services; changes in government regulation; our ability to complete capital raising transactions; and other factors (including the risks contained in the section of this Annual Report entitled "Risk Factors") relating to our industry, our operations and results of operations. Actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

### Item 1. Business

### Our Strategy

Our objective is to develop and commercialize our product candidates to treat diseases where the innate immune system is not functioning normally and contributing to the patient's disease. This can be in cancer where Natural Killer ("NK") cells are inactive and contribute to a tumor's evasion of the immune system and/or disease progression while Myeloid Derived Suppressor Cells ("MDSC") proliferate to protect the tumor from attack by the patient's immune system or this can be other diseases such as neurologic and metabolic diseases where chronic inflammation results in innate immune system dysfunction and disease progression. Our initial focus will be the treatment of cancer solid tumors and treatment of Alzheimer's Disease. In cancer, we plan to pursue two parallel development programs: (1) with INKmune our first drug candidate, we will initially focus on treating women with relapse refractory ovarian carcinoma; (2) with INB03, we will treat patients with advanced cancers with elevated biomarkers of inflammation including elevated levels of MDSC in their blood. Our third drug candidate XPro1595, targets Alzheimer's Disease which we initiated once we received a non-dilutive funding from the Alzheimer's Association as a $1 million US dollar Part-the-Cloud Award (as described below). Once resources are available, we intend to expand our development programs with INKmune, INB03 and XPro1595 into high risk Myelodysplastic Syndromes ("MDS"), a combination therapy trial with approved checkpoint inhibitors in patients with resistant or refractory to checkpoint inhibitors and other neurodegenerative diseases respectively. The principal components of our strategy to achieve this objective are to:

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- pursue development strategies and regulatory approval pathways that allow the treatment of oncology patients with our lead product candidates, INKmune and INB03;
- pursue development strategies and regulatory approval pathways that allow the treatment of neurodegenerative diseases in patients with our lead product candidates, XPro1595;
- adopt a product development strategy that solidifies our existing intellectual property ("IP") to prevent competition and expand our IP suite into related immunotherapeutic areas;
- provide clear value propositions to third-party payers, such as managed care companies or government programs like Medicare, to merit reimbursement for our product candidates; and
- enter into collaborations with other pharmaceutical companies with respect to, among other things, our INKmune and INB03 product candidates and other products that will benefit from development or marketing beyond our current resources.

*Pursue development and regulatory approval pathways.* We believe INKmune, INB03 and XPro1595 may be approvable under pathways that are potentially shorter than those typically available for drug products based on novel active ingredients, including as an orphan drug under the Orphan Drug Act and approval under the Food and Drug Administration (the "FDA") Accelerated Approval Program (see "Government Regulation"). We have not yet had a discussion with the Medicines and Healthcare Products Regulatory Agency ("MHRA") and/or FDA regarding such designation, but plan to do so in 2019. We believe both our high risk MDS and ovarian carcinoma treatment programs fit the criteria used by the FDA to grant these regulatory designations. We believe that it would take a minimum of six months to receive Orphan Drug status once we submit an application and a minimum of 12 months to receive a designation once we submit an application. We might never have these discussions, submit applications under the Orphan Drug Act as the FDA Accelerated Approval Program or have these applications approved if we do.

*Adopt a two-pronged patent strategy.* We are pursuing a two-pronged product development strategy that will seek to solidify our existing IP to prevent competition, and expand our IP suite into related immunotherapeutic areas. We are confident that our core in-licensed IP (see "Intellectual Property") will allow us both freedom-to-operate and provide robust protection from outside competition. We will continue to invest in expanding our patent suite. We will also seek to further to strengthen our IP position by looking to in-license IP related to immunotherapeutic strategies focused on the innate immune system.

*Provide clear value propositions to third-party payors to merit reimbursement for our product candidates*. We are designing our clinical development programs to demonstrate compelling, competitive advantages to patients and prescribers, and also to demonstrate value propositions to third-party payors. We believe the use of INKmune and/or INB03 in patients with a high risk of tumor progression and death from tumor should prolong survival, improve the patient's quality of life and decrease the total cost of care for patients with these lethal malignancies. For example, ovarian cancer patients relapse frequently. Each relapse requires an expensive, hospital-based treatment regimen that has decreasing benefits. Treatment with INKmune as an out-patient may provide a more durable remission and limit the need for treatment-associated hospitalizations. At the patient level, we believe INKmune and INB03 therapy, once approved, should improve survival and quality of life. At the payor level, we believe INKmune, once approved, should provide more predictable costs and outcomes. Therapies for Alzheimer's disease are needed for medical, social and economic reasons. The cost of Alzheimer's disease to the government is large and growing. The cost to families and care givers is real and burdensome. We believe treatment of patients with dementia, including Alzheimer's disease, may provide a strategy to alter the costly dynamic of this disease in society today.



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*Enter into collaborations to maximize the value of our technology.* We believe there are two reasons for us to enter into collaborations with other companies. The first is the further development of INKmune, INB03 and XPro1595 by either providing additional innovations to the product, including combination therapy strategies, and/or providing resources to improve the speed and breadth of the development process. The second is to optimize the commercialization of our products either globally or regionally. The ideal partner will benefit us in both ways.

We continue to look for ways to utilize our unique capabilities to optimize clinical application of cell therapies. We believe that we have identified a way to manufacture human mesenchymal stem cells for the medical research and biotech community that offers large volumes of high-quality, low passage human umbilical cord mesenchymal stem cells with minimal batch-to-batch variability. We believe this may solve the problem associated with supplying an adequate supply of human mesenchymal stem cells for clinical applications. The process to produce pooled, human umbilical cord mesenchymal stem cells was developed at University College London. We have established a reliable supply of human umbilical cords based on our agreement with the Anthony Nolan Cord Blood Bank in the United Kingdom. We have developed a validated manufacturing process that reliably produces contract manufacturer of the clinical grade ("cGMP") quality mesenchymal stem cells. The manufacturing process can be performed at a contract manufacturing site under the direction of Mark Lowdell, the Company's CSO. We are negotiating an exclusive license to the manufacturing process from University College London Business, the licensing organization of University College London. We will seek academic laboratories and biopharma companies who need a reliable source of high quality pooled human umbilical cord mesenchymal stem cells for research of and development of clinical products. Once identified, we plan to act as a cGMP for the development of therapeutic products by utilizing contract manufacturers. Because the production of the product is not continuous, we do not expect to engage a contract manufacturer until we have a customer identified. We have identified several contract manufacturers in the UK that have the capability to produce cGMP stem cells. To date, the investment in this project has been approximately $50,000 USD plus management time. We expect the commercial arrangement with academic laboratories or biopharma companies to be a combination of fee-for-service and licensing that does not require additional investment by us. We will be opportunistic in pursuing therapeutic opportunities for our own portfolio with this platform in the future if resources become available. The regulatory path for therapeutic applications of the mesenchymal stem cell products is well established and similar to the regulatory approval process for other cell therapies. We will only be responsible for regulatory compliance related to manufacturing of the mesenchymal stem cells when the product is being developed by a third party. When developing a therapeutic product for the Company's commercial portfolio, the Company will be responsible for all aspects of the regulatory process. The license from University College London Business unit for the manufacturing process to produce large quantities of high quality pooled, human umbilical mesenchymal stem cells is in late stages of negotiation. We cannot guarantee that the negotiations will be successful. If the negotiations are not successful, we will not pursue the mesenchymal stem cell program in the near future. As such, this program is in the very early stages of development and may not continue as a clinical program within the Company.

**Overview of Immunotherapy for Cancer**

The immune system has two parts, innate and adaptive. The innate immune system is the body's first line of defense against an infection, providing immediate, non-specific responses to eliminate harmful cells in the body. Components of the innate immune system include cytokines, chemokines, macrophages, neutrophils and NK cells, among others.

The adaptive immune system is often initially triggered by the innate immune system, mounts a delayed response against diseased cells and plays a role protecting against re-infection. An adaptive immune response is highly specific to a particular pathogen or antigen and is developed or learned from prior exposure. Key components of the adaptive immune system include antibodies which bind to antigens and mark them for destruction by other immune cells, B-cells which produce these antibodies upon exposure to antigens, and T-cells which attack and eliminate the diseased cells.

The biopharmaceutical industry has made significant advances in harnessing specific components of innate and adaptive immune systems for therapeutic use. Some of these approaches are summarized below.



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***Cytokines.*** One of the early applications of immunotherapy is the use of cytokines, including interferons and interleukin-2 ("IL-2"). Interferons are molecules that inhibit the growth and replication of diseased cells and stimulate innate immune cells to attack them. They have been used as standard of care for hepatitis B and C and multiple sclerosis, and to a lesser extent, as treatment for certain cancers, including chronic myeloid leukemia, cutaneous T-cell lymphoma, myeloma and non-Hodgkin's lymphoma. However, the use of interferons has generally decreased over the years due to serious adverse events (*e.g.*, flu-like symptoms and dramatic weight loss) and introduction of new therapies with higher efficacy, better safety profiles and more convenient administration. IL-2 activates T-cells and NK cells to attack diseased cells. IL-2 is used to treat select cancers, but due to its relatively poor safety profile, physicians often only resort to this therapy for the most advanced settings. Tumor Necrosis Factor alpha ("TNF") is the focus of INB03. TNF biology has four elements that include two cytokines, soluble TNF and trans-membrane TNF ("sTNF" and "tmTNF," respectively), and two receptors, TNF Receptor 1 and 2 ("TNFR1" and "TNFR2"). The biology of TNF ligation of TNFR varies dramatically based in what elements of the TNF system that are used. sTNF binding to TNFR1 is responsible for inflammation and cell death while sTNF binding to TNFR2 promotes proliferation of regulatory T cells ("Treg"). In patients with advanced cancers, increased sTNF is not favorable to long-term survival. tmTNF can bind either TNFR to improve the immune response, promote cell survival and stimulate remyelination. In brief, sTNF is the "bad" TNF and tmTNF is the "good" TNF. In patients with cancer, infection or neurologic disease, blockade of tmTNF function has negative consequences such as immunosuppression, increased infection and demyelination.

***Antibody therapy.*** Antibodies exist in three formats; monoclonal ("mAbs"), oligo/polyclonal and antibody-drug conjugates. mAbs represent an effective therapeutic modality and are important to the treatment paradigm of various diseases. Recent insights into the detailed mechanism of mAbs link their strong disease fighting potential to the immune system. Drug manufacturers have leveraged mAbs' ability to induce an antibody-dependent cell-mediated cytotoxicity, or ADCC effect to develop better treatments that prolong survival and quality of life of patients. In addition, mAbs designed to inhibit specific checkpoints in the immune system have demonstrated strong immune responses and therapeutic benefit in patients. However, the degree of efficacy of these therapies is heavily reliant on the immune system of patients, many of whom are severely immuno-compromised. For example, despite over $1.0 billion of sales generated by recently launched PD-1 and PDL1 checkpoint inhibitors, they are reported to be generally only effective in approximately 10% to 25% of the addressable patient population. In addition, mAbs are manufactured through a complex process that requires purification of cell products created from a cell line. Polyspecific antibodies, for example bi-specific antibodies, are able to target more than one antigen. These are often used to bring and effector T cell in contact with a target cell. Antibody drug conjugates are mAbs attached to a toxin, chemotherapy or radio therapy that delivers the cancer killing payload directly to the cancer.

***Dendritic Cell Therapies.*** This approach is designed to indirectly stimulate a patient's T-cells by leveraging the role of dendritic cells in presenting antigens to T-cells. Cancer vaccines are the most common application of dendritic cells. The only FDA-approved dendritic cell therapy is PROVENGE, which entails collecting monocytes from the patient, maturing them into dendritic cells, "loading" *ex vivo* with the patient's cancer antigens, and then re-infusing in the patient. Currently, this process is cumbersome and expensive, and again, relies on an intact and effective immune system of the patient. There are additional ongoing preclinical studies and clinical trials being conducted by our competitors aimed at addressing certain of the limitations associated with this approach. To date, current clinical results of dendritic cell therapies have been mixed.

***CAR-T and TCR Therapies.*** T-cells recognize diseased cells by receptors engaging with antigens that are present on or inside the diseased cells. CAR-T therapy entails genetically engineering T-cells to express synthetic CARs that direct T-cells to antigens on the surface of cancer cells. TCR therapy modifies T-cells to express high-affinity tumor specific TCRs that recognize intra-cellular antigens that must be presented on the surface of target cells. In early clinical trials, CAR-T and TCR therapies have demonstrated impressive anti-tumor activity in a narrow spectrum of hematologic cancers and garnered significant attention by research institutions and biopharmaceutical companies. We believe a key limitation of adaptive autologous immunotherapy is the need to retrieve non-compromised immune cells from a cancer patient which requires a complex and costly manufacturing process to develop the therapy. The complexity of this personalized process is reflected in the price of the two approved therapies. CAR-T therapies - tisagenlecleucel and axicabtagene ciloleucel for advanced leukemia and lymphoma respectively. The cost of a single therapy is many hundreds of thousands of dollars. As a consequence of this need to harvest active T-cells, current Phase I clinical trials for autologous CAR-T cell therapy in large part enroll patients from highly selected, often relatively early-stage disease in a narrow spectrum of cancers, including bulky hematological cancers. In addition, Phase I clinical trials of CAR-T cell immunotherapy have reported severe adverse toxicities of cytokine release syndrome and neurotoxicity, requiring hospitalization, pre-conditioning and, in some instances, intensive care unit admission following side effects associated with cytokine release syndrome. As a result, though our competitors continue to develop their CAR-T and TCR product candidates with the goal of addressing certain of the limitations associated with these approaches, we believe these serious challenges may limit their potential and use in a variety of indications, including solid tumors.



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***Checkpoint Inhibitors.*** Immune cells express proteins that are immune checkpoints that control and down-regulate the immune response. These are best defined in T lymphocytes and include PD-1, CTLA-4, TIM-3 and LAG3. Tumor cells express the ligands to these receptors. When T cells bind the ligand to these proteins on the tumor cells, the T cell is turned off and does not attempt to attack the tumor cell. Thus, checkpoint inhibitors ("CPI") are part of the complex strategy used by the tumor to evade the patient's immune system and are responsible for resistance to immunotherapy. Biopharmaceutical companies have successfully developed CPI that block the receptor/ligand interaction to promote the adaptive immune response to the tumor. Six CPI are currently approved, pembrolizumab, nivolumab, atezolizumab, avelumab, durvalumab, and ipilimumab for a wide variety of solid tumors including melanoma, lung, bladder, gastric cancers and others. More CPI are in development and more tumor types will be added to the list of sensitive tumors over the next years. CPI have become the backbone of cancer therapy and are expected to be the best -selling class of drugs by 2027.

***NK Cells.*** NK cells typically represent approximately 2% to 13% of circulating lymphocytes and are a critical component of the immune system responsible for innate immunity. Unlike adaptive immune cells, they are ever present and ready to attack, having the inherent ability to detect and eliminate diseased cells without the need for antigen presentation, which is why they are called "natural killers."

NK cells bind to stress ligands expressed by the diseased cells and directly eliminate them. This binding induces NK cells to release cytokines, including, interferons and GM-CSF, which are integral in recruiting additional innate and adaptive immune responses by the host. NK cells also represent a critical effector cell for ADCC, whereby target cells bound with human antibodies, whether made by the patient's body or administered, are selectively destroyed by the NK cells.

***MDSC Cells:*** MDSC are present in very low quantities in healthy patients. MDSC develop and proliferate in patients with chronic infection and with cancer. In cancer, MDSC are a unique and well-defined cell population that home to the cancer and secrete immunosuppressive cytokines that provide a protective, immunosuppressive shield to the tumor. This protective immunosuppressive shield prevents the patient's immune system from attacking the tumor. The presence of MDSC in the tumor microenvironment and/or circulating in the patient's blood predict for more advanced disease, resistance to immunotherapy and a worse patient survival.

**INKmune: Our NK cell Directed Product Candidate**

INKmune is our lead product candidate that converts resting NK cells into primed NK cells, an essential step in them becoming activated cancer-killing NK cells. We have shown this works ex vivo in human tissue cell cultures, and we believe that this will work in vivo which is the purpose of our planned clinical trials.

- Cancers grow and relapse because they evade the immune system. NK cells are the most important cell for the elimination of residual disease that causes cancer relapse. NK cells target cells based on a series of complex antigens on the cancer cell surface that signal the NK cells to activate and kill the cancer cell. We call these cancer antigens "priming signals" and "triggering signals" respectively. An NK cell must receive a series of multiple signals through a network of cell surface receptors constituting of both priming and triggering signals. Crucially, we have shown that the priming signals can be delivered independent of the triggering such that one cell, such as INKmune, may deliver priming signals and the patient cancer cell deliver the second set and induce killing. Cancer cells defective in priming signals evade NK killing so the cancer cell survives and grows. Both priming and triggering signals are not a single surface molecule on the NK cell, but a complex combination of signals from multiple cell surface ligands which lead to NK priming and triggering respectively. Cancer cells also express molecules which can inhibit NK cell priming and triggering and the final outcome of the NK-cancer cell conjugation is a balance of all of these signals. In summary, INKmune shifts that balance of stimulating and inhibitory signals to enhance the ability of resting NK cells to kill a wide range of patient cancers. [Sabry Lowdell Frontiers, North et al JI and Sabry et al JI and Tsirogianni et al AmJ Hematol]. This concept is shown in the schematic form in Figure 1 below.



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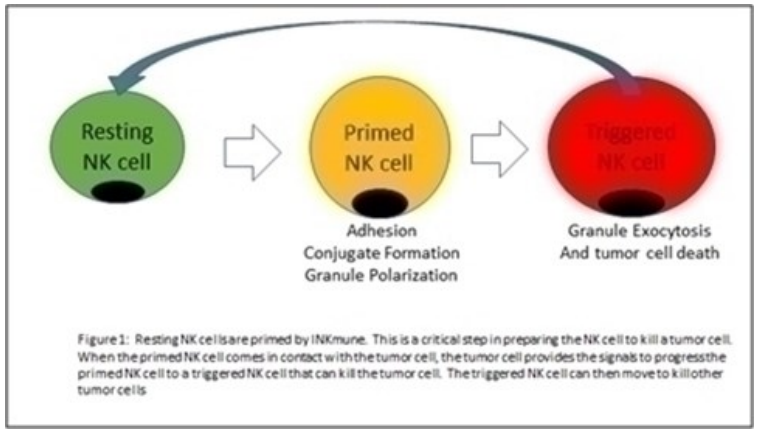


Figure 1: Resting NK cells are primed by INKmune. This is a critical step in preparing the NK cell to kill a tumor cell. When the primed NK cell comes in contact with the tumor cell, the tumor cell provides the signals to progress the primed NK cell to a triggered NK cell that can kill the tumor cell. The triggered NK cell can then move to kill other tumor cells

- The main "job" of a cancer cell is to survive and grow. Unfortunately, the "successful" cancer cell ultimately kills the host. The first priority for survival is to evade NK cell killing. The vast majority, >98%, of cancer cells do this by downregulating expression of priming ligands. When an NK cell interrogates a cancer cell lacking sufficient priming signals the NK cell is unable to trigger lysis. This allows the cancer to evade NK cell killing to grow, and, we believe, is one of the causes of cancer relapse.

- We have described the functional biology underlying the interaction of NK cells and cancer cells. We believe that we have learned to counteract the loss of the priming signals by artificially providing these signaling ligands to the resting NK cell by exposure to a proprietary tumor cell line which constitutively expresses them. We call this product candidate INKmune. When we deliver INKmune to a resting NK cell, it provides priming signals to convert the resting NK cell in to a tumor primed NK cell ("TpNK"). TpNK are poised to kill any cancer cell that expresses adequate triggering ligands. Based on our extensive pre-clinical testing, we believe this covers a large and heterogenous array of primary human cancers including hematologic malignancies such as acute myelogenous leukemia, multiple myeloma, lymphoma, and solid tumors such as breast, prostate, renal, lung, and ovarian cancer. The TpNK binds to the cancer cell, becomes an activated NK cell that will kill the cancer cell that was previously resistant to NK cell killing. Based on the pre-clinical data, we believe INKmune will convert the patient's resting NK cells to primed NK cells will allow the patient's NK cells to kill their tumor.

- We believe there are advantages of NK cells primed with INKmune (TpNK) compared to cytokine primed NK cells ("LAK") or monoclonal antibody targeted NK cells ("MabNK"). Both LAK and MabNK require the priming/targeting agent to be present at all times for the NK cell to be a cancer killing cell. As soon as the cytokine or Mab are removed, the NK cell becomes a resting NK cell that cannot kill the cancer cell. INKmune provides a sustained "on" switch even after the INKmune reagent has been removed. Once INKmune causes the resting NK cell to become a TpNK, the NK cell remains primed and ready to kill until its lytic capacity has been exhausted by lysis of tumor cells. The second advantage is that TpNK do not require a specific target compared to MabNK. Trastuzumab (Herceptin™), a Mab targeting HER2 on breast cancer is an illustrative example. Women with HER2 positive breast cancer, 20% of all women with breast cancer, can be treated with and benefit from Herceptin immunotherapy. Unfortunately, the other 80% who are HER2 negative, have a worse survival rate because they can not avail themselves to Trastuzumab immunotherapy. INKmune may benefit the women with HER2 negative breast cancer. We believe the pre-clinical and clinical data using tumor primed NK cells indicates that signals delivered by cancer cells are adequate to provide priming and activation of NK cells to kill the cancer and possibly eliminate the need for MabNK.



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- We have demonstrated TpNK killing of many tumor types in laboratory studies. Tumor priming is effective regardless of the source of the NK cells and in many types of tumors – both cell lines and primary tumors from patients. The principle of TpNK killing has also been demonstrated in two Phase I trials in patient with acute myelogenous leukemia ("AML"). These trials were not supported by us and used a first-generation personalized cell therapy product. In these trials, haplo-identical NK cells obtained from a first degree relative by leukapheresis were primed ex-vivo using a lysate of a tumor cell. Once the TpNK therapy has been produced and passed quality testing, the patient received conditioning therapy with chemotherapy (cyclophosphamide and fludarabine), the

primed haplo-identical NK cells were given to patients by intravenous infusion. Two Phase I clinical trials have been performed using the first-generation treatment strategy. An investigator initiated trial performed at the Royal Free Hospital in London 2005 was funded by a UK charity. Fifteen patients with relapsed, high-risk AML were enrolled in the trial. Because of drop-out due to disease progression, delays in product production and complications of conditioning therapy, only 7 of the fifteen patients were treated with the TpNK cell product. Four of seven patients showed clear benefit from the treatment with the TpNK product with prolonged relapse free remission and, in one patient, conversion of a partial remission to full remission. None of the remissions were durable; all patients ultimately died from disease progression. The safety of the product was found to be a combination of toxicity from the chemotherapy conditioning regimen and the TpNK therapy. In general, the complications were well tolerated although did require medical intervention including prolonged periods of aplasia in two heavily pretreated patients that resolved with supportive care. The results of this study have been published in a medical journal (PLoS One. 2015 Jun 10;10(6):e0123416. doi: 10.1371/journal.pone.0123416. eCollection 2015). In 2013, a second open label, multi-center trial was performed in the US using virtually the same product and procedures but targeting a slightly different patient population. In the second trial, 12 patients in first remission with AML were treated with the haplo-identical TpNK product produced using the first generation ex-vivo priming process. After conditioning with chemotherapy, the patients received TpNK in three dosing cohorts – 3x10^5, 1x10^6 or 3X10^6 TpNK per kilogram. Patients were followed for safety and relapse free survival. This trial confirmed the safety of the TpNK treatment in patients with AML and reinforced many of the efficacy findings seen in the first trial. Patients benefited from haplo-identical TpNK therapy with prolonged relapse free survival including two patients that remain in remission more than 42 months after treatment. This trial has been published. (Biol Blood Marrow Transplant. 2018 Mar 26. pii: S1083-8791(18)30132-0. doi: 10.1016/j.bbmt.2018.03.019.) The results of the laboratory and Phase I studies provide evidence that our strategy for treating residual disease is sensible but unproven.

- Because INKmune primes NK cells to target naturally occurring antigens, we believe INKmune can be used in to treat a wide variety of cancers including hematologic malignancy (AML, MM, CML, high risk MDS) and solid tumors (renal, prostate, breast, ovarian, pancreas and lung). We expect the list of INKmune sensitive tumors to continue to expand.

- The primary role for INKmune will be an immunotherapy targeting residual disease in patients after debulking cancer therapies such as cytotoxic chemotherapy and surgery. At this time, we plan to give INKmune as monotherapy. We do not rule out the possibility of using INKmune as part of combination therapy in the future. We do not expect to need to modify INKmune to treat these additional types of cancer, because we believe INKmune is a universal cancer therapy where "one size fits all". We believe for INKmune to receive regulatory approval for each cancer indication, clinical trials will need to be performed which demonstrate its safety and effectiveness as a treatment for each such cancer. We believe the difficulty and cost of achieving these labels extensions will decline with each successive approval, if and when achieved. For example, if INKmune is proven to be effective therapy in patients with ovarian cancer and high-risk MDS, we will need to perform separate pivotal trials for approval in lung, prostate or renal cancer.



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**Three step process to preparation for INKmune human clinical trials:**

*INKmune GMP scale-up for Phase I/II clinical material*

We have contracted with, Advent Bioservices, a contract manufacturing organization to produce the master cell bank for INKmune using good manufacturing practice, or GMP, clinical material. Advent Bioservices used GMP manufacturing facilities leased from the Centre of Cell, Gene and Tissue Therapeutics ("CCGTT") at the Royal Free Hospital. The working cell banks and individual INKmune product to be used in the patients for the clinical trial will be produced at the Royal Free Hospital in the CCGTT. All manufacturing has been under the direction of Professor Mark Lowdell. The Company is on target to produce enough INKmune to complete the Phase I/II clinical trials in women with ovarian cancer and in patients with high-risk MDS by the end of the second half of 2020. We may need additional INKmune for future clinical trials. Planning for site of manufacture and the financing for that manufacturing has not been made at this point.

*INKmune Biomarker Development Program*

We have discovered two biomarker strategies that we believe can be used to demonstrate: i) who should receive INKmune therapy; ii) if the INKmune therapy is working; and iii) when INKmune therapy should be repeated. For the initial Phase I/II trials in patients with ovarian cancer, we expect the biomarker testing will be performed in a single laboratory under our direction. In the near future, we will develop assay systems with standard operating procedures to ensure uniform testing of the biomarker across clinical sites. This will facilitate expansion of the clinical programs to multiple sites. We anticipate that, in the future, the biomarker program may be a surrogate marker for both clinical effectiveness and marketing purposes.

*Interaction with Regulatory Authorities Regarding INKmune Development*

We met with the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the UK version of the FDA as part of a Scientific Advice Meeting in September 2017. The purpose of the meeting was to explain to the MHRA our manufacturing process and clinical plan for the development of INKmune in a Phase I/II trial in relapse/refractory ovarian cancer. The MHRA provided positive feedback on our manufacturing and clinical plans. We submitted a Clinical Trial Authorization ("CTA") in the fourth quarter of 2018 to support the ovarian cancer Phase I/II trial in the United Kingdom, which was accepted on December 18, 2018. We are in the process of completing the steps to open two clinical sites to perform the Phase I portion of the clinical trial. We have not chosen sites for the Phase II portion of the clinical trial.



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*INKmune Product Development Path Proposed Phase I/II Study in patients with cancer*

By the first quarter of 2019, we plan to initiate an open label Phase I/II cancer study in patients with ovarian carcinoma. Patients will be enrolled who have a low burden of relapse refractory disease and have peripheral blood or ascites NK cells which can respond to INKmune in a laboratory test on NK function. The study design agreed upon after discussion with the MHRA on September 12, 2017 will be a two-step Phase I/II study. In the Phase I to be performed under a CTA issued on at the University College of London Hospital in London and South Hampton University Hosptials, both clinical sites in the UK. We expect to initiate trial by the second quarter of 2019. In the Phase I trial, women with relapse refractory ovarian cancer will be treated with INKmune, given as an intra-peritoneal infusion through an indwelling peritoneal catheter in a traditional open label study to demonstrate safety and determine the dose of INKmune to be carried into the larger Phase II portion of the study. Based on pre-clinical studies that indicate that women with relapsed/refractory ovarian cancer have NK cells in their peritoneal cavity that response to INKmune to kill SKOV3, an ovarian cell line, we believe intra-peritoneal delivery of INKmune will be therapeutically effective. Three clinical trials support this observation. Two clinical trials have been performed using the first generation haplo-identical TpNK product in patients with AML. Both of those studies have been published (PLoS One. 2015 Jun 10;10(6):e0123416. doi: 10.1371/journal.pone.0123416. eCollection 2015) and (Biol Blood Marrow Transplant. 2018 Mar 26. pii: S1083-8791(18)30132-0. doi: 10.1016/j.bbmt.2018.03.019.). In summary, the studies showed that TpNK therapy, when delivered by intravenous infusion after conditioning therapy, was effective in providing prolong remissions with a toxicity profile that was manageable. TpNK therapy has not been delivered via intraperitoneal infusion, but a similar treatment

strategy is used for the delivery of TALL-104 cells. TALL-104 is a replication incompetent human MHC non-restricted cytotoxic T-cell leukemic cell line that has been extensively studied and used to treat a number of cancers. Currently, Galileo Research, an Italian biotech company, has used TALL-104 in a Phase II clinical trial to treat women with ovarian cancer (http://www.galileoresearch.it/en/pipeline/TALL-104.html). In that study, TALL-104 is delivered via intraperitoneal infusion. Although the efficacy of the therapy is not yet known, the therapy is well tolerated with toxicities mainly related to the infusion catheter, not related to the TALL-104 infusion. The primary end points of the INKmune Phase I trial are safety and determining the dose of INKmune to take into the Phase II portion of the clinical trial. The key secondary efficacy end-points to be studied are i) increased NK cell priming as determined by multicolor flow cytometry of NK cells from the patient; ii) increased NK cell killing of SKOV3 tumor in a bioassay as shown in Figure 2 below; and iii) a decrease in tumor burden as measured by CA125 levels in the blood. Once safety and the optimal INKmune dose have been determined, a randomized study of women treated with INKmune will be compared to a group of control patients who receive only standard of care. We expect to treat six patients in the Phase I portion of the trial, but this number can increase by as many as 18. The Phase II portion of the protocol will enroll 30 patients in a 2:1 randomization (20 active: 10 control). In both trials, in addition to immunologic monitoring of NK activation status and ability to kill tumors, CA125, a serologic biomarker of tumor burden and medical imaging studies of tumor burden will be used to determine the effect of INKmune therapy on the patient's ovarian cancer. The primary end-point in the Phase II portion of the study will be improved relapse free survival in INKmune patients compared to control patients. Secondary end-points should provide evidence of improved immunologic function, improved NK medicated killing of tumor cells in a bioassay and a decrease in tumor burden by both imaging and measurement of CA125 in blood. The Phase II proof-of-concept study should allow us to accurately design future studies for regulatory approval. The dose and frequency of intraperitoneal INKmune therapy will be finalized during the Phase I portion of the trial. We are planning at least 5 treatments with of INKmune therapy IP over a 3 month period. If patients are responding, the attending physician may decide to extend the therapy beyond the planned therapy as compassionate use. We are prepared to support these patients with INKmune therapy as dictated by their response to therapy. The Phase II portion of the study will be expanded to other clinical sites in the United Kingdom. We may choose to open Phase II clinical sites in the US. This will require us to submit an Investigational New Drug (IND) application to the FDA using the Phase I data.

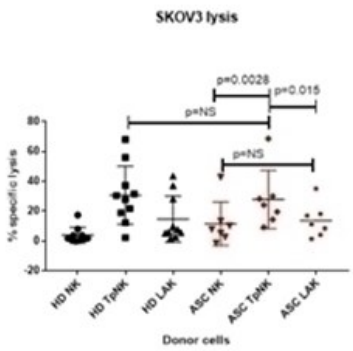


Figure 2: INKmune primed NK cells kill SKOV3, a NK resistant ovarian cancer cell line, in an *in vitro* tumor killing assay. NK cells from healthy donors (HD NK) or patient NK cells isolated from ovarian patient ascites (ASC NK) do not kill SKOV3. After priming NK cells with INKmune, healthy donor (HD TpNK) and patient (ASC TpNK) NK cells kill significantly more SKOV3 cells than unprimed NK cells from healthy donors (HD NK) or patients (ASC NK). IL2 primed NK cells from healthy donor (HD LAK) or ovarian cancer patient ascites (ASC LAK) do not kill SKOV3 tumor cells. INKmune primed NK cells from patients (ASC TpNK) and from healthy donors (HD TpNK) are equally effective in killing SKOV3 tumor cells.



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*INKmune Registration Studies and/or Partnering*

After completion of proof-of-concept Phase II studies with INKmune, we will decide whether to continue to develop INKmune as a treatment for ovarian carcinoma indication and/or expand into other tumor types such as high risk MDS. We expect to have biopharma partners participate in this decision. We may also seek to be acquired at this stage or partner INKmune. Although our development strategy is focused on North America and Europe, we believe INKmune will also be attractive for markets on the Pacific Rim, South Asia and South America, but will wait for partners to help with the development in those regions, however, at this time, we are not negotiating with any potential partners.

*INKmune Regulatory Strategy*

INKmune is a new therapy for the treatment of cancer that will need to be proven safe and effective by well-designed clinical trials that show a meaningful clinical benefit to patients. We believe that registration trials will need to be designed as randomized trials in patients with cancer where one group of patients received INKmune and another receive best available care. We received advice from the MHRA on September 12, 2017 on the design clinical trial for ovarian cancer. We plan to perform the Phase I trial with INKmune in the United Kingdom under a clinical trials authorization ("CTA"). We plan to expand the Phase II program to additional sites in the United Kingdom and the US. We will meet with the FDA once we have data from the Phase I trial. We plan to file an IND with the FDA to allow us to expand the Phase II clinical trial in to the US. Because there are no therapies similar to INKmune approved in any market, we plan to take advantage of the regulatory opportunities afforded to therapies that treat small markets with a high unmet need. In the U.S., this includes Orphan Drug Designation and expedited programs for approval including Accelerated Approval, Breakthrough Therapy Designation, Fast Track Designation, and priority review (see "Government Regulation"). We cannot predict which of these programs we will benefit from, if any at all, without further discussions with the FDA. Similar programs exist in the EU with the European Medicines Agencies ("EMA").

*Emerging Market Opportunity*

The cancer therapy market is large, diverse and competitive. Although the concept of immunotherapy with monoclonal antibodies has been around for more than 20 years, the concept that patient derived immunosuppressive factors was a barrier to effective cancer treatment was recently recognized and had its first therapy approved just four years ago (ipilimumab, Yervoy, BMS, March 2011). Since then, five additional "check point" inhibitors have been approved, but the market is in its infancy. Most of the focus on strategies for modulating tumor-based immunosuppression focus is on the adaptive immune system ("T-cells"). The role of, and the importance of manipulating the innate immune system has more recently become a target of therapeutic development. NK cells are part of the innate immune system and are critical in both tumor surveillance (prevention) and treatment (killing). Myeloid Derived Suppressor Cells ("MDSC") are part of the innate immune system that only appear once the patient has chronic inflammation, a common occurrence in patients with cancer. The main role of the MDSC is to protect the tumor from attack by the patient's immune system. Because T-cell focused strategies do not have an effect on the innate immune system, patient's receiving such treatments may fail to recruit half of the patient's immune system, the innate immune system, to attack the patient's cancer. Clinicians increasingly recognize that durable responses to cancer require a coordinated attack by the patient's adaptive and innate immune system. Normalizing the response of the innate immune system requires eliminating the dysregulated innate immune response that decreases the patient's ability to see and attack the cancer as well as mechanisms the protect the cancer from immunologic attack (effector and protector function respectively). INKmune primes NK cells to enable them to attack the tumor. INB03, by decreasing the proliferation and function of MDSC, will lessen the immunosuppressive shield that protects the tumor from immunologic attack and, through NK/DC crosstalk, recruit the adaptive immune system to the fight.

**Challenges in the Market for Our Product Candidates**

The market for new oncology therapies is busy, complicated and rapidly evolving. We will be competing with companies that are older, larger, better financed and have greater experience. There are two types of drug companies – development companies and commercial companies. Development companies take the risk of developing new products to proof-of-concept. Once proof-of-concept has been achieved, if the drug provides clinical benefit, the product is usually acquired by a commercial company, which completes the drug's clinical development and markets the product. We are a development company which will seek to develop products such as INKmune from the bench to the bedside to demonstrate proof-of-concept. The goal for us is to successfully develop such products to the point where they are attractive targets for potential partners/acquirers.



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According to a recent Markets and Markets report, the immunotherapy market is growing rapidly at an annual rate of over 13%. Recently, the market is biased towards T cell-based immunotherapies including bi-specific antibody therapies, checkpoint inhibitors and CAR-T cell-based therapies. There are substantial numbers of clinical trials that are focused on the adaptive immune system versus clinical trials that are focused on the innate immune system for the treatment of cancer. Our challenge will be to educate partners on the value of NK cell-based therapeutic strategies. The need to educate people of the importance of INB03 is equally challenging. At the academic level, there is recognition that therapies targeting MDSC are needed to improve the results of immunotherapies. Investors and potential partners are only now learning about MDSC. We will be responsible for educating them on the importance of MDSC and why INB03 may be an important addition to the oncologist's armamentarium. We believe educating investors and partners about new therapeutic opportunities is an easier task than trying to differentiate our company from the many other cancer immunotherapy companies. We plan to use a combination of publication, presentation and investor relations to promote INKmune and INB03 and to educate the clinical, biopharma and investor community on the value of these novel therapeutic approaches.

**INKmune Competition**

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, price and reimbursement level. Many of our potential competitors, including many of the organizations named below, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than us in obtaining FDA approval for and achieving widespread market acceptance of their drugs. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Further, the development of new treatment methods for the conditions we are targeting could render our drugs non-competitive or obsolete.

INKmune is an immunotherapy that harnesses the biology of NK cells for the treatment of cancer. There is a long list of immunotherapy strategies for the treatment of cancer and the immunotherapy for cancer market is growing rapidly. There are at least three ways to classify immunotherapy for cancer. The list below classifies immunotherapy strategies beginning with those that are most closely related to INKmune:

1. Companies in the NK cell therapy business;

2. Companies in the personalized immune-oncology business; and

3. Companies in the precision immuno-oncology business.

We are not aware of any approved treatments that are classified as NK cell therapies. We are aware of three public companies in the NK cell therapy business: NantKwest, Fate Therapeutics and Fortress Biotech. These companies are developing products that involve replacing or supplementing NK cells of the patient for the treatment cancer. Their product requires extensive ex-vivo cell manipulations which, with respect to NantKwest and Fate Therapeutics, may include gene therapy. The next larger group of companies are in the personalized immuno-oncology business with products focused on T cell activation strategies. The most popular are the CAR-T cell therapies which are a patient specific ex-vivo gene therapy approach to a single disease (for example: pediatric ALL). CAR-T therapy has become wildly popular of late and includes many private companies, newer public companies such as Bluebird, Juno Therapeutics and Mustang Bio as well as established companies such as Novartis and Gilead. For many of the companies, CAR-T cell therapies is their only business. For the latter two, CAR-T cell therapies is a newly in-licensed program with marketing authorization in the US. Finally, the precision immune-oncology category also includes companies with anti-cancer antibody products and the newer "check-point" inhibitors. Antibody therapies are all about "illuminating" the cancer to the innate immune system (NK cells). Monoclonal antibodies were the original immunotherapy that drove the growth of well-known biopharma companies including Genentech/Roche, Amgen, Merck and others. Each of these products is disease specific (ie: treat only HER2+ breast cancer). Modern therapeutic antibodies are much more complicated bi-specific and tri-specific antibodies that attempt to connect the cancer with activated T-cells of the adaptive immune system. Check-point inhibitors are currently the most rapidly expanding product category in immuno-oncology. These CTLA-4 (ipilimumab) and PD-1 inhibitors (pembrolizumab and nivolumab) specifically block a mechanism that shields cancers from T-cell killing. The two companies in this business are Merck (pembrolizumab) and GSK (ipilimumab and nivolumab). There are many others trying to join this promising therapeutic area including large companies such as BMS and Roche.



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There are a number of FDA approved drugs that improve the ability of the innate immune system (NK-cells) to treat cancer including mono-clonal antibody therapies (for example: Rituximab®; Avastin® and Herceptin® marketed by Roche/Genentech); and "check-point" inhibitors (Yervoy® and Opdivo®, BMS, Keytruda®, Merck and others). There is a large amount of development activity in the immune checkpoint inhibitor field from both pharmaceutical giants including AstraZeneca, Merck & Co, Pfizer, Merck KGaA, Roche, GSK, Novartis and Amgen and many start-ups, small companies and university spin-offs which have emerged in the past two years. Examples (in alphabetical order) include Agenus, Alligator Bioscience, Ambrx, AnaptysBio, argenx, Bioceros, BioNovion, Cellerant Therapeutics, Checkpoint Therapeutics, Compugen, CureTech, Enumeral, Five Prime Therapeutics, Genmab, GITR, ImmuNext, IOmet Pharma, iTeos Therapeutics, Jounce Therapeutics, KAHR Medical, Multimeric Biotherapeutics, Nativis, Orega Biotech, Pelican Therapeutics, Pieris Pharmaceuticals, Prima BioMed, Redx Pharma, Sorrento Therapeutics, Tesaro, TG Therapeutics, Theravectys and ToleroTech active in the field. The list of companies with poly-specific antibodies that attempt to link the cancer with a cytotoxic T cell is long, includes both private and public companies (Amgen, Xencor, F-Star, Merus and many others). Finally, two CAR-T cell therapies were just approved for the treatment of ALL – Kymriah™ (Novartis) and Yescarta™ (Gilead). We expect additional drugs to gain marketing authorization in the immune-oncology space.

To our knowledge, there are three companies with NK cell immunotherapies in development. The first is Fortress Biotech (NASDAQ:FBIO) which is developing CNDO109 for the treatment of AML. CNDO109 is an allogeneic ex-vivo NK cell activation program that utilizes live cancer cells to prime the related donor's NK cells. The primed NK cells are then given to the patient with AML. This program has entered a Phase I clinical trial in the US; the results of the trial highlighted in a previous section have recently been published. Prof. Mark

Lowdell, a founder of this Company, performed a single center trial in the United Kingdom using almost identical technology as CNDO109. We believe that the results of the trial were promising with several patients having a prolonged remission after a single treatment (Kottaridis et al. (2015). PLoS ONE 10(6):1-19). NantKwest, (NASDAQ Global Select Market) is an early stage biotech company that is using a genetically engineering strategy of a NK cell line to produce a live, off-the-shelf NK cell product to treat a variety of cancers. The clinical data for this product is sparse at this time. Fate-NK 100 and Engineered hnCD16iNK from Fate Therapeutics are product candidates designed to replace or supplement NK cells in patients with cancer. For the practice reports that this enrolling a trial with Fate-NK 100 in women with relapsed/refractory ovarian cancer.

To our knowledge, there are no innate immune check-point inhibitors in development that have the unique characteristics of INB03 that neutralize sTNF to: i) decreases the proliferation of MDSC; ii) decreasing local and systemic immunosuppression caused by MDSC by stopping production of immunosuppressive cytokines and; iii) improving NK/DC cross-talk to recruit the adaptive immune system to fight the cancer.



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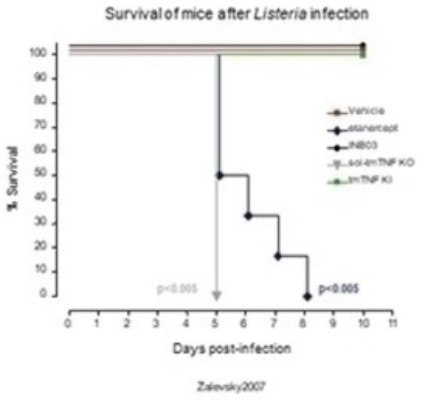
**INB03 Competition**

To our knowledge, there are no other innate immune system check-point inhibitors in development that combine the characteristics of decreasing the population and function of MDSC while promoting NK/DC crosstalk that expands and recruits the adaptive immune response to attack the patient's tumor. Lilly is developing LY3022855, a human IgG1 monoclonal antibody designed to target the CSF1R that should inhibit MDSC from receiving CSF1 signals, decreasing their survival and relieving the effect of MDSC in the tumor. Daiichi Sankyo Inc., in collaboration with Bristol Myers Squibb, is testing DS-8273a, a TRIAL-R2 agonistic antibody in combination with a PDL1 inhibitor to decrease the number of MDSC in patients with colorectal cancer. Rgenix Inc., is developing RGX-104, an orally bioavailable small molecule immunotherapy that targets LXR (liver X Receptor). RGX-104 reportedly depletes MDSC. Syntrix Biosystems is developing SX-682. SX-682 is a small-molecule dual-inhibitor of CXCR1 and CXCR2, the chemokine receptors pivotal to tumor metastasis, therapy-resistance, and myeloid cell suppression of cancer surveillance by the adaptive immune system. By blocking the CXCR1/2 pathway, SX-682 may prevent recruitment of MDSC to the tumor microenvironment. The University of Minnesota has a trivalent antibody program aimed at treating patients with advanced hematologic malignancies. This CD16/IL-15/CD33 (161533) Tri-Specific Killer Engagers (TriKes) product may target CD33+ MDSC. Siamab Therapeutics is developing an anti-sialyl-Tn monoclonal antibody that targets MDSC in some tumor types. Clathera Biosciences, in collaboration with Incyte, a US based biotech, is developing CB-1158 (INCB01158), an arginase inhibitor to decreases MDSC. A Phase II clinical trial is open that combines CB-1158 with nivolumab, an anti-PD1 CPI marketed by Bristol Myers Squib. Reata Pharmaceuticals is testing omaveloxolone (RTA 408) in the phase Ib/II REVEAL trial in combination with either ipilimumab (Yervoy) or nivolumab (Opdivoo) in patients with advanced unresectable or metastatic melanoma. Currently approved non-selective TNF inhibitors, infliximab, etanercept, adalimumab and others, are not considered direct competitors of INB03 in the treatment of cancer because of their mechanism of action and safety side effects. Non- selective TNF inhibitors block the function of both sTNF and tmTNF. Blockade of tmTNF is immunosuppressive increasing the risk of infection and cancer in patients. This is shown in Figure 3 below where maintaining function to tmTNF by genetic or pharmacologic means results in an immunocompetent animal that can protect itself against infection. Blockade or knock-out of both sTNF and tmTNF results in death from infection.

Figure 3: INB03 does not cause immunosuppression, a known safety side-effect of currently available non-selective TNF inhibitors, because INB03 does not block transmembrane TNF. In this model, CBL/6mice are given a sublethal dose of Listeria then have TNF function manipulated by genetic knock-out or by pharmacologic treatment. Normal all animals survive the sublethal infection (red). Animals with a double soluble and transmembrane knock-out die quickly (gray). Mice with a single gene knock-out (tmNF KI, have) functional trans-membrane TNF all survive (green). The pharmaceutical experiment mimics the results of the genetic KO experiment. Double blockade of soluble and transmembrane TNF with etanercept causes animals to die quickly (blue) while animals treated with INB03 that neutralizes soluble TNF while preserving transmembrane TNF function all survive (black). This experiment demonstrates that the cause of immunosuppression seen with currently available non-selective TNF inhibitors is an off-target effect of trans-membrane TNF blockade and that INB03 does not cause immuno-suppression.




**Intellectual Property**

The INKmune product candidate is protected by a family of patents pending in the United States Patent & Trademark Office (the "USPTO"), in the International Bureau of the World Intellectual Property Organization ("WIPO") under the Patent Cooperation Treaty ("PCT"), and in patent offices for various foreign jurisdictions. We generally enter national stage under the PCT in Australia, Canada, Europe, and Japan, sometimes in China and/or Korea. The following table summarizes our pending and granted patent positions at the time of preparing this document:



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INKmune (Cancer)

The INKmune product candidate is protected by a family of patents pending in the United States Patent & Trademark Office ("USPTO"), in the International Bureau of the World Intellectual Property Organization ("WIPO") under the Patent Cooperation Treaty ("PCT"), and in patent offices for various foreign jurisdictions. We generally enter national stage under the PCT in Australia, Canada, Europe, and Japan, sometimes in China and/or Korea. The following table summarizes our pending and granted patent positions at the time of preparing this document:

| Patent/ Application | Number | Name | Jurisdiction | Ownership | Type | Expiration Date |
|---|---|---|---|---|---|---|
| Application | 15/268,399 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | USA | Licensed | Method | TBD |
| Application | PCT/US2016/061835 | "IN VIVO PRIMING OF | PCT-GLOBAL | Licensed | Method | N/A |

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|---|---|---|---|---|---|---|
| | | NATURAL KILLER CELLS" | | | | |
| Application | 3,009,171 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | CA | Licensed | Method | TBD |
| Application | 16847576.2 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | EP | Licensed | Method | TBD |
| Application | 2018-534524 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | JP | Licensed | Method | TBD |
| Application | PCT/US2018/022722 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | PCT-GLOBAL | Licensed | Method | N/A |
| Application | 2018203469 | "IN VIVO PRIMING OF NATURAL KILLER CELLS" | AU | Licensed | Method | N/A |

INB03 (Cancer) & XPRO1595 (Neurologic Diseases)

The patent suite for INB03 covers patents related to DN-TNF technology, including XPRO1595. This patent suite continues to expand with active prosecution on use of INB03 in cancer and neurologic diseases. We will continue to expand the use of this therapy to other areas.

| Patent/ Application | Number | Name | Jurisdiction | Ownership | Type | Expiration Date |
|---|---|---|---|---|---|---|
| Patent | US 7662367 | PHARMACEUTICAL COMPOSITIONS FOR THE TREATMENT OF TNF-ALPHA RELATED DISORDERS | USA | Licensed | Composition | 12/19/2026 |
| Patent | US 7446174 | PROTEIN BASED TNF-ALPHA VARIANTS FOR THE TREATMENT OF TNF-ALPHA RELATED DISORDERS | USA | Licensed | Composition | 8/9/2026 |
| Patent | EP 1578988 | PROTEIN BASED TNF-ALPHA VARIANTS FOR THE TREATMENT OF TNF-ALPHA RELATED DISORDERS | EPO | Licensed | Composition | 4/14/2025 |



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| Patent | JP 4353802 | PROTEIN BASED TNF-ALPHA VARIANTS FOR THE TREATMENT OF TNF-ALPHA RELATED DISORDERS | JPO | Licensed | Composition | 4/14/2025 |
| Patent | US 7687461 | TREATMENT OF TNF-ALPHA RELATED DISORDERS WITH TNF-ALPHA VARIANT PROTEINS | USA | Licensed | Composition | 11/17/2026 |
| Patent | US 7244823 | TNF-ALPHA VARIANTS PROTEINS FOR THE TREATMENT OF TNF-ALPHA RELATED DISORDERS | USA | Licensed | Composition | 3/31/2024 |
| Patent | US 7056695 | NOVEL TNF-a VARIANTS | USA | Licensed | Composition | 3/2/2021 |
| Application | 14/427,279 | METHODS OF TREATING NEUROLOGICAL DISEASES | USA | Licensed | Method | TBD |
| Application | 13766804.2 | METHODS OF TREATING NEUROLOGICAL DISEASES | EUROPE | Licensed | Method | TBD |
| Application | PCT/US2018/053227 | TREATMENT OF COMPLICATIONS RELATED TO ACUTE OR CHRONIC HYPERGLYCEMIA | USA | Jointly-Owned | Method | N/A |
| Application | 62/804,133 | METHODS FOR TREATING NEURO INFLAMMATION | USA | Owned | Method | N/A |
| Application | 15/776,061 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | US | Licensed | Method | TBD |
| Application | 2016876541 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | EP | Licensed | Method | TBD |
| Application | 2016371907 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | AU | Licensed | Method | TBD |
| Application | 3006767 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | CA | Licensed | Method | TBD |



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|---|---|---|---|---|---|---|
| Application | 20168073849 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | CN | Licensed | Method | TBD |
| Application | 1020187020449 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | KR | Licensed | Method | TBD |
| Application | 2018531185 | "CANCER PREVENTION AND THERAPY BY INHIBITING SOLUBLE TUMOR NECROSIS FACTOR" | JP | Licensed | Method | TBD |

Our commercial success depends in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot assure you that our pending patent applications will result in issued patents.

- "N/A" is used above with respect to provisional patent applications and international PCT patent applications, each of which is only temporary in nature, and does not mature into a valid enforceable patent by itself, but instead serves to establish a chain of priority rights for subsequently filed patent applications.

- "TBD" is used above with respect to pending patent applications which are undergoing ordinary patent prosecution and may eventually issue as a valid enforceable patent.

International PCT patent applications cover all 152 nations which are signatories of the PCT. However, our IP strategy generally recognizes the United States, United Kingdom, European Union, Canada, Japan, Australia and China as targets for extending patent protection under the PCT. Decisions regarding which countries to extend patent coverage under the PCT is taken on a case by case basis, subject to normal business considerations such as value and return on investment

On July 04, 2017, the USPTO allowed U.S. Trademark Serial No. 87/124,324 for the mark "INB16" in I.C. 001 & 005. We intend to complete registration upon use of the mark in commerce.

On March 08, 2017, the USPTO allowed U.S. Trademark Serial No. 87/124,304 for the mark "INMUNE" in I.C. 042. We intend to complete registration upon use of the mark in commerce.

On February 21, 2017, the USPTO allowed U.S. Trademark Serial No. 87/124,324 for the mark "INKMUNE" in I.C. 001 & 005. We intend to complete registration upon use of the mark in commerce.

*Immune Ventures, LLC License Agreement*

On October 29, 2015, we entered into an exclusive license agreement with Immune Ventures, LLC, the owner of all of the rights related to our principal patent (the "Immune Ventures Agreement"). Pursuant to the Immune Ventures Agreement, we were granted exclusive worldwide, sub-licensable, royalty-bearing licenses (collectively "Patent Rights") as well as all applications (the "Field") of the Patent Rights, including rights to incorporate any improvements or additions to the patents that may be developed in the future to the following patents and patent applications:



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***Patent Applications:***

| ***Property No.*** | ***Patent Application Serial No.*** | ***Filing Date:*** | ***Title:*** |
|---|---|---|---|
| (1) | US 62/219,652 | 09/16/2015 | IN VIVO ACTIVATION OF NATURAL KILLER CELLS |
| (2) | US 62/263,951 | 12/07/2015 | IN VIVO ACTIVATION OF NATURAL KILLER CELLS |
| (3) | US 15/268,399 | 09/16/2016 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (4) | PCT/US2016/061835 | 11/14/2016 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (5) | US 62/471,953 | 03/15/2017 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (6) | CA 3,009,171 | 06/19/2018 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (7) | EP 16847576.2 | 04/16/2018 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (8) | JP 2018-534524 | 04/16/2018 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (9) | PCT/US2018/022722 | 03/15/2018 | IN VIVO PRIMING OF NATURAL KILLER CELLS |
| (10) | AU 2018203469 | 05/16/2018 | IN VIVO PRIMING OF NATURAL KILLER CELLS |

***Patents:***

| ***Property No.*** | ***Patent No.*** | ***Issue Date:*** | ***Title:*** |
|---|---|---|---|
| (N/A) | N/A | N/A | N/A |

In consideration for the Patent Rights, we agreed to the following milestone payments (of which none have been incurred as of December 31, 2018):

| | |
|---|---|
| Each Phase I initiation | $ 25,000 |
| Each Phase II initiation | $ 250,000 |
| Each Phase III initiation | $ 350,000 |
| Each NDA/EMA filing | $ 1,000,000 |
| Each NDA/EMA awarded | $ 9,000,000 |

In addition, we agreed to pay the licensor a royalty of 1% of net sales during the life of each patent granted to us. The Licensor is owned by Raymond J. Tesi, our President and a member of our Board of Directors, David Moss, our Chief Financial Officer and Treasurer and Mark Lowdell, our Chief Scientific Officer. In countries where a claim of an issued and unexpired patent or a pending claim in a pending patent application within the Patent Rights exists a royalty of nine percent of net sales of each of each licensed product shall be paid for the remaining life of each patent on a country by country basis.

The term of the Immune Ventures Agreement began on October 29, 2015 and, if not terminated sooner pursuant to the agreement, ends on a country by country basis on the date of the expiration of the last to expire patent rights where patent rights exists. Subject to granting, prosecution-related patent term adjustments, and requirements for maintenance and renewals, the latest to expire patent is scheduled to expire on March 15, 2038 ("Natural Expiration"). Upon Natural Expiration of the Immune Ventures Agreement, we shall have a fully paid up, perpetual, royalty-free license without further obligation to Immune Ventures. The Immune Ventures Agreement can be terminated by Immune Ventures if, after 60 days from our receipt of notice that we have not made a payment under the Immune Ventures Agreement we still do not make this payment. Under the agreement and an amendment to the agreement dated July 20, 2018, we are required achieve the following milestones:



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Filing of IND or equivalent, by October 29, 2019;
Initiation of Phase 1 clinical or equivalent trials by October 29, 2020;
Initiation of Phase II clinical trials or equivalent by October 29, 2022;
Initiation of Phase III clinical trials or equivalent by October 29, 2024; and
Filing of NDA or equivalent by October 29, 2025 or equivalent.

If we don't achieve the above milestones, we are required to negotiate in good faith with Immune Ventures to determine how we can either remedy the failure or achieve an alternate development. If we fail to make any required efforts or if the efforts do not remedy the situation within 60 days of written notice by Immune Ventures then Immune Ventures may provide notice to terminate the license or convert it to a non-exclusive license.

*University of Pittsburg License Agreement*

On October 3, 2017, the Company entered into an Assignment and Assumption Agreement with Immune Ventures related to intellectual property licensed from the University of Pittsburgh. Pursuant to the Assignment and Assumption Agreement (the "Assignment Agreement"), Immune Ventures assigned all of its rights, obligations and liabilities under an Exclusive License Agreement between the University of Pittsburgh – Of the Commonwealth System of Higher Education ("Licensor") and Immune Ventures to INmune Bio ("Licensee"), (the "PITT Agreement"). Pursuant to the Assignment Agreement, the Company agreed to convert the amount Immune Ventures paid of $162,634 into shares of the Company's common stock at $7.71 per share, based on the per share value of the shares issued to Xencor, for 21,094 shares for the reimbursement of amounts paid by the Assignor to the University of Pittsburgh, which the Company recorded as stock-based compensation within research and development expense. These shares were issued on December 31, 2017.

Consideration under the PITT Agreement includes: (i) annual maintenance fees, (ii) royalty payments based on the sale of products making use of the licensed technology, and (iii) milestone payments.

Annual maintenance fees under the PITT Agreement include: $5,000 due June 26 of each year 2018-2022; $10,000 due on June 26 of each year 2023-2024; and $25,000 due on June 26 of each year 2025 and annually thereafter until first commercial sale.

| | | |
|---|---|---|
| June 26 of each year 2018-2022 | $ | 5,000 |
| June 26 of each year 2023-2024 | $ | 10,000 |
| June 26 of each year 2025 until first commercial sale | $ | 25,000 |

Upon first commercial sale of a product making use of the licensed technology under the PITT Agreement, the Licensee is required to pay royalties equal to 2.5% of Net Sales each calendar quarter.

Moreover, under the PITT Agreement the Licensee is required to make milestone payments as follows:

| | | |
|---|---|---|
| Each Phase I initiation | $ | 50,000 |
| Each Phase III initiation | $ | 500,000 |
| First commercial sale of product making use of licensed technology | $ | 1,250,000 |

A Phase I study was initiated in 2018, and the Company recorded $50,000 of research and development expense during the year ended December 31, 2018 pursuant to this milestone payment schedule. The PITT Agreement expires upon the earlier of: (i) expiration of the last claim of the Patent Rights forming the subject matter of the PITT Agreement; or (ii) the date that is 20 years from the effective date of the agreement (June 26, 2037).



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Licensee may terminate the PITT Agreement upon 3 months prior written notice provided all payments under the license are current. Licensor may terminate the PITT Agreement upon written notice if: (i) Licensee defaults as to performance of material obligations which have not been cured within 60 days after receiving written notice; or (ii) Licensee ceases to carry out its business, becomes bankrupt or insolvent, applies for or consents to the appointment of a trustee, receiver or liquidator of its assets or seeks relief under any law for the aid of debtors.

*Xencor License Agreement*

On October 3, 2017, the Company entered into a license agreement with Xencor, Inc., which has discovered and developed a proprietary biological molecule that inhibits soluble tumor necrosis factor (the "Xencor Agreement"). Pursuant to the Xencor Agreement, Xencor granted the Company an exclusive worldwide, royalty-bearing license in licensed patent rights, licensed know-how and licensed materials (as defined in the Xencor Agreement) to make, develop, use, sell and import any pharmaceutical product that comprises, contains, or incorporates Xencor's proprietary protein known as "XPRO1595" that inhibits soluble tumor necrosis factor (or all modifications, formulations and variants of the licensed protein that specifically bind soluble tumor necrosis factor) alone or in combination with one or more active ingredients, in any dosage or formulation. In connection with the Xencor Agreement, we paid Xencor a one-time non-creditable and non-refundable fee of $100,000 and agreed to issue Xencor 1,585,000 shares of our common stock. We also issued warrants to Xencor which are discussed below.

We also agreed to pay Xencor a royalty of 5% on net sales of all Licensed Products in a given calendar year, which are payable on a country-by- country and licensed product by licensed product basis until the date that is the later of (a) the expiration of the last to expire valid claim covering any pharmaceutical product that contains, comprises, or incorporates Xencor's proprietary protein known as XPRO1595 alone or

in combination with one or more active ingredients, in any dosage or formulation. ("Licensed Product") in such country or (b) ten years following the first sale to a third party of the licensed product in such country. Net Sales with respect to any Licensed Product is the gross amounts invoiced by us for sales of the Licensed Products less deductions actually incurred.

Under the Xencor Agreement, we also agreed to pay Xencor a percentage of any sublicensing revenue that it receives equal to (i) 60% of sublicensing revenue received in respect of any sublicense granted prior to initiation of a Phase 1 Clinical Trial of a Licensed Product in the applications for the treatment of disease in humans (the "Field"); (ii) 30% of Sublicensing Revenue received in respect of any sublicense granted on or after initiation of a Phase 1 Clinical Trial of a Licensed Product in the Field and prior to initiation of a Phase 2 Clinical Trial of a Licensed Product in the Field; (iii) 15% of Sublicensing Revenue received in respect of any sublicense granted on or after initiation of a Phase 2 Clinical Trial of a Licensed Product in the Field and prior to initiation of a Phase 3 Clinical Trial of a Licensed Product in the Field; (iv) 10% of Sublicensing Revenue received in respect of any sublicense granted on or after initiation of a Phase 3 Clinical Trial of a Licensed Product in the Field and prior filing of the first NDA application for any Licensed Product in the Field; and (v) 5% of Sublicensing Revenue received in respect of any sublicense granted on or after the approval of the first NDA application for any Licensed Product in the Field. For clarity, initiation of a clinical trial shall mean dosing of a first patient in said clinical trial.

A valid claim is an issued, unexpired or pending claim with the patent rights that Xencor controls as of October 3, 2017 which patent rights are necessary to make, develop, use, sell, have sold, offer for sale and import a Licensed Product in the Field (the Field means all applications for the treatment of diseases in humans) or the Product Patent Rights, which claim has not lapsed, been abandoned, been revoked or been held to be unpatentable, invalid or unenforceable by a final judgment of a court or other governmental agency or competent jurisdiction from which no appeal can be or is taken within the time allowed for appeal and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise. Product Patent Rights shall mean any and all our patent rights that are necessary to make, develop, use, sell, have sold, offer for sale and import a Licensed Product in the Field, including any improvements or patent rights directed to the Licensed Product. Either party may terminate the Xencor Agreement upon 60 days' (10 days for any payment default) prior written notice to the other party after the breach of any material provision of the agreement by the other party if the breaching party has not cured the breach within the 60-day period (10-day period for any payment default) following written notice of termination by the non-breaching party. We can terminate the Xencor Agreement upon 180 days prior written notice to Xencor. Xencor may terminate the Xencor Agreement in its entirety or with respect to any specific Licensed Product upon written notice in the event that we contest, oppose or challenge or assist any party in contesting, opposing or challenging, Xencor's ownership of, or the enforceability or validity of the Patent Rights that Xencor controls as of October 3, 2017 which Patent Rights are necessary to make develop, use, sell, have sold, offered for sale and import a Licensed Product in the Field. Either party may terminate the Xencor Agreement upon written notice to the other party upon or after the insolvency, bankruptcy, dissolution or winding up of such other party or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party or the initiation of proceedings in voluntary or involuntary bankruptcy which proceeding or action remains undismissed or unstayed for a period of more than 60 days.



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In connection with the Xencor Agreement, we entered into a stock issuance agreement with Xencor pursuant to which it agreed to issue Xencor 1,585,000 shares of its common stock with a fair value of $12,221,000 based on the discounted cash flow method of the income approach as set forth in an independent valuation report from HSSK LLC dated November 17, 2017, and fully vested warrants to purchase an additional number of shares of common stock equal to 10% our the fully diluted company shares immediately following such purchase with a fair value of $4,193,000 based on the Black-Scholes Option Pricing model. In August 2018, we entered into a First Amendment to Stock Issuance Agreement. Pursuant to the amendment, the purchase price for the additional shares may only be paid by cash.

In connection with the stock issuance agreement, we, Xencor and more than 90% of shareholders as of September 30, 2017 ("Key Holders") entered into a voting agreement. Pursuant to the voting agreement, Xencor and the Key Holders agreed to vote their respective shares to vote one individual designated by the holder of a majority of Xencor's shares of our common stock to our board of directors. The voting agreement shall continue in full force and effect until the earliest of: (a) the date of a qualified offering, as defined in the issuance agreement; (b) ten (10) years from the date of this Agreement; (c) the date of the closing of a qualified sale, as defined in the issuance agreement; or (d) the date as of which the parties hereto terminate this agreement by written consent of the holders of a majority of the Investor Shares.

**INKmune Research and Development**

We expect to use third parties to conduct our preclinical and clinical trials under the direct supervision of management.

*Joint Development Agreement*

On September 3, 2016, we entered into a joint development agreement with Novamune, Inc. ("Novamune") (the "Development Agreement"). Novamune had previously developed and licensed technology relating to ex-vivo activation of NK cells for the treatment of cancer and other diseases. The parties agreed to exclusively collaborate on the further development of technologies related to NK cells for therapeutic applications. We will share equally in the costs related to such joint development projects and will jointly own any intellectual property developed by the joint projects, provided that Novamune shall have an exclusive royalty free license to use any such intellectual property relating to ex-vivo applications, and we shall have an exclusive royalty free license to use any such intellectual property relating to in-vivo applications. The Development Agreement is subject to Novamune investing a total of $1,250,000 in our Company, of which $350,000 has previously been advanced through a convertible note payable. The balance of $900,000 was invested on February 9, 2018 in exchange for 400,000 shares of common stock. The Development Agreement ends on September 3, 2023 unless terminated sooner. The term of the Development Agreement may be extended for one year upon the written consent of both parties. The Development Agreement may be terminated prior to the end of the term by either party in the event of a material breach by the other party of the terms of the Development Agreement, provided that the terminating party is not in breach and has first given the defaulting party written notice of termination specifying the grounds for the terminating and if after giving the defaulting party 30 days to cure the breach, the breach was not cured.

**INKmune Manufacturing**

We intend to contract with third parties for the manufacture of our compounds for investigational purposes, for preclinical and clinical testing and for any FDA approved products for commercial sale. Pre-clinical and clinical material for the early clinical trials with INKmune has been manufactured under the direction of Mark Lowdell and Advent Bioservices International, our strategic partner, at a licensed Good Manufacturing Practice ("GMP") facility. The master cell bank, working cell bank and individual product doses were completed in July 2018. This clinical material is planned for use in the Phase I/II clinical trials in ovarian cancer. If we raise adequate capital to initiate the high-risk MDS Phase I/II trials, additional working cell banks and therapeutic product will be produced from the existing master cell bank. This process takes approximately 6 months and is not anticipated to delay the initiation of the high-risk MDS Phase I/II trials. We may transfer the manufacturing to a different commercial contract manufacturing organization after completion of these Phase II studies.



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**Human Mesenchymal Stem Cells**

In November 2017, we entered into a Material Transfer and License Agreement with the Anthony Nolan Cord Blood Bank ("AN"), the oldest and largest non-directed cord blood bank in the United Kingdom for the supply the starting material for the mesenchymal stem cells - umbilical cords not used after cord blood harvest. Mark Lowdell's research group developed and validated a methodology for producing large numbers of clinical-grade pooled human umbilical cord derived mesenchymal stem cells ("HucMSC"). We believe the reproducible and reliable supply of large quantities of high-quality a may solve one of the major problems associated with the development of mesenchymal stem cell therapies for medicine. Under this agreement we were granted a license to produce and sell these cells for medical research, including clinical trials. The agreement provides that Immune Bio Internal shall pay to AN £200 plus VAT (if applicable) for each umbilical cord tissue sample (and any intellectual property, developed, or conceived by Immune Bio International in exercising its rights under the agreement ("Licensed Product")) Immune Bio International receives pursuant to the agreement. Additionally, during the entire term of the agreement, Immune Bio International shall pay AN a royalty of 2% of the net sales of the Licensed Product. We believe we are well positioned to become a preferred manufacturing partner for companies who need MSC for clinical programs. Manufacture of HucMSC is performed under the direction of Mark Lowdell in a licensed GMP facility that is contracted to the Company as part of existing research and development agreements. The starting material for the HucMSC product is provided by the AN. The HucMSC product produced in this facility are fully qualified to be used for either research or clinical trials. Currently, we plan to supply HucMSC to third parties for their research use and in clinical trials as part of the development process for commercial pro/ducts. We may decide to expand this agreement in the future if the commercial and/or development opportunities warrant such expansion. At the current time, we expect this program to be funded by revenues from commercial sales. The agreement with AN terminates on November 29, 2027. AN may terminate the license on written notice to us, if a donor withdraws consent to the continued use of umbilical cord tissue samples that were obtained by AN. Additionally, either party may terminate the agreement on 30 days prior written notice to the other if that other party materially breach any term of the agreement and such breaches (to the extent it is remediable) is not remedied within 30 days of the written request to the other party to do so.

**Our Innate Immune System Check-point inhibitor product candidate**

We renamed XPRO1595, which we license from Xencor, to INB03 when it is used for cancer related indications. We will continue to call the drug XPRO1595 when used for treatment of neuropsychiatric diseases, including Alzheimer's disease discussed below. INB03 and XPRO1595 are the same drug with different names for marketing purposes. INB03 is a novel innate immune system check-point inhibitor that we believe prevents proliferation of MDSC and decreases the secretion of immunosuppressive cytokines that protect the tumor from the patient's immunologic attack and help make the tumor resistant to immunotherapy. INB03, by inhibiting soluble TNF without inhibiting trans-membrane TNF or TNF receptors ("tmTNF" and "TNFR" respectively), alters the immunoregulatory cell and cytokine profile of the tumor microenvironment to decrease the population of MDSC, decrease immunosuppressive cytokines and increase immunoregulatory cytokines that changes the patient's immune response to their tumor with improved NK/DC crosstalk that causes expansion of the immune response including recruitment of the adaptive immune system with an increase in effector and cytotoxic T cells that attack the cancer. After treatment with INB03, we believe the patient's dysregulated immune response, a hallmark of cancer progression and resistance to therapy, to be converted to a coordinated immune response that can attack in combination with immunotherapy. These immune responses have been studied in animal models of an inflammatory cancer, where 3-methylcholanthrese is given to mice in a subcutaneous injection that causes the development of multiple cutaneous fibrosarcoma. This model was developed by Y Akamatsu in 1967 while working at the National Cancer Institute of the NIH. In research published by Professor Nikola Vujanovic in *Cancer Immunology Research* in 2016, treatment with INB03 resulted in smaller and fewer cancers with increased survival. INB03 is an engineered PEGylated protein that neutralizes human soluble TNF, a human inflammatory cytokine that is increased in patients with advanced cancer. By specifically neutralizing the cytokine, there is decreased phosphorylation of STAT3, an essential step required for the proliferation of the MDSC population, and secretion of the immunosuppressive cytokines. The combination of decreased MDSC proliferation and decreased immunosuppressive cytokines allows the immune system to respond to the tumor. This data was published in an article entitled Inhibition of Soluble Tumor Necrosis Factor Prevents Chemically Induced Carcinogenesis in Mice in Cancer Immunology Research in *Cancer Immunology Research* 2016. In summary, INB03 functions as an innate immune system checkpoint inhibitor by eliminating the population of MDSC that provides an immunosuppressive shield protecting the tumor, the patient's immune system is able to function normally to the benefit of the patient – it can attack the tumor.



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Because INB03 targets the patient's immune system and not the tumor, we believe INB03 is an immunotherapy that can be used to treat many types of hematologic malignancies and solid tumors as part of combination therapy. The decision to use INB03 in a patient will be based on biomarkers that should predict that a patient will benefit from treatment with the drug. MDSC rarely exist in patients without cancer or chronic inflammation. Because MDSC can be measured in the tumor and/or blood of patients with immune dysregulation and chronic inflammation caused by their cancer, MDSC blood levels i) have prognostic value predicting cancer stage and risk of dying from cancer; ii) may be used as a biomarker to target patients who will benefit from INB03 therapy and iii) should be biomarkers demonstrating a pharmacodynamic effect of INB03 therapy. We believe, if MDSC are present in significant numbers, the patient should benefit from INB03 treatment as part of combination therapy. Basing treatment decisions on the presence of MDSC is a precision medicine, biomarker directed immunotherapy strategy that should improve the probability of benefiting a patient and improve the value of INB03 therapy and decrease the risk of the clinical development process. Although, INB03 can be used as part of combination of anti-cancer therapy including, but not limited to, cytotoxic chemotherapy, immunotherapy, radiation therapy and/or surgery, our Phase I clinical trial will focus on using INB03 as monotherapy. This is a typical Phase I clinical trial design for first-in-man trials in cancer. We expect to use INB03 as part of combination therapy with approved checkpoint inhibitors as part of Phase II development. We do not expect to need to modify INB03 therapy to treat each different type of cancer, because INB03 therapy targets the immune system, not the cancer. We do expect to develop the INB03 beyond Phase II to target a specific type of cancer to meet the current system of regulatory approval. For instance, INB03 may be approved to treat patients with elevated MDSC who have lung cancer. To get subsequent approval for the treatment of patients with breast cancer who have increased MDSC, we will need to perform a pivotal trial in women with breast cancer. After the first regulatory approval, if and when achieved, we believe the difficulty and cost of achieving these labels extensions will decline with each successive approval. At this time, we cannot rule out if patients with biomarkers of inflammation without elevated MDSC in blood, or patients without biomarkers of inflammation or MDSC in their blood will benefit from treatment with INB03. Those studies may be performed in the future, but they are not a priority.

XPro1595 has neutralizes soluble TNF in the brain in exactly the same way INB03 neutralizes soluble TNF in the tumor microenvironment but the effects of soluble TNF neutralization in the brain are different. The cause of the destructive neuroinflammation in the brain is the microglial cell. The microglial cell is one of four cells in the neural unit that also includes astrocytes, oligodentrocytes and nerve cells. Activated microglial cells are considered the resident macrophages of the brain. The primary role of microglial cells is to protect the neural unit from infection. When innate immune dysfunction causes chronic inflammation, activated microglial cells produce soluble TNF that activates astrocytes. Activated glial cells cause nerve cell and oligodrocyte dysfunction that results in synaptic pruning, nerve cell death and demyelination of neurons. These pathologies contribute, in part, to neurodegenerative diseases such as AD, Parkinson's disease, ALS, MS, Huntington's disease, glaucoma and schizophrenia and may contribute to neuropsychiatric diseases such as depression, bi-polar disease, sleep disorders, autism and PTSD. In the setting of AD, microglial activation causes dendritic pruning, synaptic dysfunction and nerve cell death that contributes to cognitive decline and the behavioral manifestations of AD including depression, aggressiveness, sleep disorders, hallucinations and anhedonia. Elimination of microglial activation should reverse these symptoms. Because soluble TNF is the apex cytokine in the inflammatory cytokine cascade, neutralization of soluble TNF with XPro1595 should prevent glial activation and normalizes function of the neural unit.

INB03 and XPro1595 is delivered as a subcutaneous injection, similar to an insulin treatment, given one to three times per week. Because this is a simple subcutaneous injection similar to an insulin injection (the therapy patients give themselves for treatment of Type 1

diabetes mellitus), we expect patients to administer the therapy to themselves and not require expensive or logistically challenging clinic visits to receive the therapy



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Three step process to preparation for INB03 and XPro1595 human clinical trials:

*Release of INB03 and XPro1595 drug supply*

GMP INB03 and XPro1595 are available for clinical development after completion of release testing. The annual process for release testing was completed in February 2018 and January 2019. The process started in November 2017 and October 2018 respectively. The supply of INB03 is limited, but enough to complete the planned Phase I and Phase II studies in oncology. The re-release dossier has been submitted to the regulatory authorities in Australia. We received notification on May 21, 2018 that the INB03 can be used for clinical trials in AUS. For future trials, new batches INB03 and XPro1595 will need to be produced. We plan to use a two-step approach to production of the new drug supply. We hope to improve the yield of the drug product using the existing *E.coli* based system. Once the new process is validated and functional, we will perform a manufacturing campaign when resources are available. We do not expect the drug supply to limit the clinical development program in oncology. We expect to start the process of manufacturing improvements and scale-up after results of the Phase I trial are known and have a validated and more efficient manufacturing process in place before the initiation of pivotal trials. We have begun discussion with contract manufacturers to make new batches of drug product.

*Interaction with Regulatory Authorities Regarding INB03 and XPro1595 Development*

We plan to perform the Phase I and Phase II trials with INB03 in Australia under the regulatory authority of the TGA using the Clinical Trials Exemption ("CTX") scheme. Our first interaction with the regulatory body occurred in March 2018. The Company received approval to initiate the Phase I trial with INB03 in patients with advanced solid tumors on May 21, 2018. We have not started the regulatory process for the combination therapy trial of INB03 with a checkpoint inhibitor. We expect combination trials to begin in 2019 once the INB03 monotherapy Phase I trial has completed patient enrollment. We have not started the regulatory process for the combination therapy trial of INB03 with a checkpoint inhibitor. The regulatory process for the development of XPro1595 for the treatment of patients with AD started in the fourth quarter of 2018. The Company received approval to initiate the Phase I trial with XPro1595 in patients with AD on February 8, 2019.

*INB03 Product Development Path: Proposed Phase I and Phase II Studies in patients with cancer*

Phase I study: We plan an open label, biomarker directed, dose escalation study in patients with metastatic epithelial cancer and elevated biomarkers of systemic inflammation including MDSC in their blood. We expect these patients to have Stage III or Stage IV cancer. Most, if not all patients will have received and failed or progressed after several lines of therapy that may have included immunotherapy. A minimum of nine patients will be treated in three dosing cohorts for three months. Patients will receive INB03 by subcutaneous injection once a week during the duration of the study. We cannot rule out longer treatment of the patients at the discretion of the treating physician. We are prepared to support the patient's treatment with INB03 until disease progression. The goal of the Phase I trial is to assess safety, determine a dose to carry in to the Phase II trial, and verify the utility of our biomarker strategy. Although it is difficult to predict safety and toxicity in Phase 1 studies, based on pre-clinical studies in rodents and non-human primates, a dose-limiting toxicity has not been identified. Immunosuppression and demyelination, the primary complications of currently available non-selective TNF inhibitors do not occur with INB03 because it does not inhibit trans-membrane TNF, the cause of immunosuppression and demyelination. Secondary end-points for the Phase I trial will include a decrease of inflammatory cytokines and MDSC in the blood. Although we will follow the stage and degree of tumor burden via imaging studies, we do not expect patients to have a significant survival benefit from this study. The most probable tumor types with be patients with breast, lung, GI cancer and melanoma. The dosing cohorts are expected to be 0.3 mg/kg, 1.0 mg/kg and 3.0mg/kg once a week. The Phase I trial will be performed at two or three private Phase I units in AUS. We have contracted with the AUS subsidiary of a multinational clinical research organization, CTI Inc., of Cincinnati, OH, to manage this study and negotiate these agreements. We started enrolling patients in the August 2018. The Phase I trial will be expanded to include combination therapy arms with immunotherapy in preparation for the Phase II study.



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Phase II study: We are planning a combination study of INB03 in combination with currently approved checkpoint inhibitors ("CPI") for the Phase II trial. Elevated levels of inflammatory biomarkers including MDSC in the blood is a predictor of treatment failure in patients with melanoma and lung cancer treated with checkpoint inhibitors. It is now recognized the myeloid cells of the tumor microenvironment including MDSC are a barrier to the efficacy of most immunotherapies because of the production of immunosuppressive cytokines that suppress the patient's immune response to the tumor. Because the best anti-tumor response requires participation of both the innate and adaptive immune system, we believe combination therapy where INB03 decreases the levels of MDSC and improves NK/DC cross-talk to recruit the adaptive immune system in combination with CPI to prevent resistance of the tumor to T cell attack will be an effective treatment of patients who have been resistant to CPI because of elevated levels of MDSC. The design of the planned biomarker directed Phase II trial is tentative. At this time, we plan to treat patients with advanced lung cancer or melanoma who have failed previous therapy that included a checkpoint inhibitor and have increased biomarkers of inflammation including increased inflammatory cytokines and elevated levels of MDSC in their blood. The Phase II will be an open label randomized trial where patients receive combination therapy with both INB03 and a CPI or receive sequential therapy with INB03 followed by CPI. INB03 will be given once a week by subcutaneous injection. Therapy will occur for at least six months – probably longer. Based on the mechanism of action of INB03 and the biology of the safety problems associated with CPI use, the safety profile of combination therapy with INB03 and CPI is expected to be manageable. The primary end-point of the Phase II trial will be progression free survival as determined validated measures of tumor progression such as imaging studies of tumor size. Immunologic parameters including levels of inflammatory cytokines and MDSC in blood will also be followed closely. Both the Phase I and II trials will be performed in Australia using the Clinical Trial Notification ("CTN") regulatory process that is administered by the TGA. The exact design of the Phase II development program may be changed by results obtained in the Phase I trial and/or by a development partner. If resources permit, we may open Phase II clinical trial sites in the US under the regulatory authority of the FDA.

*INB03 Registration Studies and/or Partnering*

We plan to aggressively pursue an efficient registration strategy using INB03 to improve the lives of patients with cancer and biomarkers of inflammation and elevated MDSC. We believe that this is not the only cancer indication INB03 can be used for. For example, we have reported that women with HER2 positive breast cancer who are resistant to trastuzumab due to expression of MUC4 may benefit from combination therapy with INB03. We plan to pursue other indications in cancer as resources become available. We have an active partnering position as it relates to INB03 development in cancer, although no partnering discussion are underway at this time. There are two partnering opportunities with this novel innate immune system check-point inhibitor. The first is a traditional partnership focused on the developing the drug for all oncology applications. The second is a more focused partnership developing INB03 as part of a combination therapy for a company's existing therapy, most probably an approved CPI. For example, CTLA4 targeted checkpoint inhibitors do not work well when given to melanoma patients with increased MDSC in their blood. A company with a CPI may want to combine INB03 with their product in a clinical development program. After completion of proof-of-concept Phase II studies, we will decide what the most efficient registration strategy is available to the company with INB03.

Our INB03 platform can be used in cancer patients in many ways. It can be used alone or in combination with, but not limited to, other cancer therapies including cytotoxic chemotherapy, immunotherapy, radiation and surgery. We expect INB03 will be used most commonly as part of combination therapy. We believe that INB03 can also be used to treat many types of hematologic and epithelial cancers. Patients with increased MDSC can be identified by examining the tumor specimen and/or blood. Patients with increased MDSC in the tumor or blood have more advanced disease, more resistance to immunotherapy and worse survival.

*INB03 and XPro1595 Regulatory Strategy*

INB03 is a new therapy for the treatment of cancer that will need to be proven safe and effective by well-designed clinical trials that show a meaningful clinical benefit to patients. This means that registration trials will need to be randomized trials in patients with cancer. The Phase I is designed as an open label dose escalation trial in patients with metastatic solid tumors. We will not limit the tumor type until we understand the best type of patient to treat with. Once we understand these important issues, we plan to seek advice from the competent regulatory authorities and clinical thought leaders to allow the Company to design clinical trials that meet the needs for registration. After completing the Phase I trial, we will perform a Phase II trial in patients with advanced melanoma or lung cancer who have biomarkers of inflammation in their blood. The Phase II trial will include patients who have failed first line therapy. The study will be an open label randomized trial comparing INB03 in combination with CPI compared to INB03. Both trials will be performed in Australia using the CTN system under the authority of the Therapeutic Goods Administration ("TGA"). We will meet with the FDA after completion of the Phase I trial. We may to expand the Phase II trial to the US under the authority of the FDA. Studies will be expanded to Europe and beyond as resources permit. Because there are no therapies similar to INB03 approved in any market, we plan to take advantage of the regulatory opportunities afforded to therapies that treat small markets with a high unmet need. In the U.S., this includes Orphan Drug Designation and expedited programs for approval including Accelerated Approval, Breakthrough Therapy Designation, Fast Track Designation, and priority review (see "Government Regulation"). We cannot predict which, if any, of these programs we will benefit from without further discussions with the FDA. Similar programs exist in the EU with the EMA. We will engage the EMA once we have initiated Phase II trials in the United States and Australia.



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*Immunotherapy for Treatment of Alzheimer's Disease*

XPro1595 is being developed for the treatment of Alzheimer's disease. XPro1595 is identical to INB03 in every way but name. The name XPro1595 will be used as the drug name in the Alzheimer's disease development program. Microglial activation and neuroinflammation are important causes of the synaptic dysfunction and nerve cell death that causes cognitive decline in patient with dementia and Alzheimer's disease. The relationship between β amyloid plaques and tau neurofibrillary tangles, the traditional targets in AD drug development and neuroinflammation is complex. We believe targeting plaques and tangles is not an effective treatment strategy, but that targeting neuroinflammation, the final common pathway of synaptic dysfunction and nerve cell death is. Substantial direct pre-clinical data supports the use of XPro1595 in murine models of AD. Substantial indirect data supports use of XPro1595 in humans including a decreased risk of AD in patients treated with non-selective TNF inhibitors for rheumatoid arthritis and treatment using direct injection into paraspinous venous plexus. Because of different mechanism of action of XPro1595 compared to the non-selective TNF inhibitors, we expect a lower risk of immunosuppression and demyelinating diseases such as MS.

We are planning an open label, biomarker directed, Phase I clinical trial in AUS that approaches AD as an immunologic disease. Patients with mild-to moderate dementia who have the diagnosis of AD with a hs-CRP>2 mg/L. a biomarker of chronic inflammation will be treated with XPro1595 for 12 weeks. Three dosing cohorts are planned -30, 90 and 180 mg per week as a subcutaneous injection. Patients will have 5 groups of inflammatory biomarkers test before therapy, at 6 weeks and at 12 weeks. Biomarkers will be tested in blood and cerebral spinal fluid, white matter free water will be determined by MRI and a "breath test" measuring exhaled volatile organ compounds will be used to determine a signature of inflammation in AD patients. Finally, behavioral biomarkers of fatigue, depression aggression, anhedonia and sleep disorders, behaviors that are very sensitive to neuroinflammation, will be cataloged using validated scales to determine if these behaviors improve as neuroinflammation is brought under control. We will be testing traditional measures of AD in blood, CSF and cognition, but we do not expect significant changes in a 12 week trial. If AD patients treated with XPro1595 tolerate the therapy well, and show improvement in biomarkers of neuroinflammation, the company may decide to pursue a larger, longer, fully powered randomized Phase II trial to determine if prolonged treatment of neuroinflammation results in less cognitive decline in patients treated with XPro1595. Funding for the Phase I trial is provided by a combination of the Part-the-Cloud Award from the Alzheimer's Association and company funding including rebates from the AUS R&D rebate scheme. If the Phase I is successful, additional funds will be needed to support execution of the Phase II trial and to produce additional XPro1595 to support the clinical programs.

*XPro1595 Registration Studies and/or Partnering*

We plan to aggressively pursue an efficient registration strategy using XPro1595 to improve the lives of patients with AD and biomarkers of inflammation. We believe AD is not the only indication for XPro1595 in neurodegenerative and neuropsychiatric diseases. We plan to pursue other indications in neurodegenerative diseases as resources become available. We have an active partnering position as it relates to XPro1595 development in neurodegenerative and neuropshyciatric diseases, although no partnering discussion are underway at this time. There are two partnering opportunities with this novel immunotherapy for the treatment of neurologic and psychiatric diseases. The first is a traditional partnership focused on the developing the drug for all neurodegenerative and neuropsychiatric applications. The second is a more focused partnership developing XPro1595 as part of a combination therapy for a company's existing therapy. After completion of proof-of-concept Phase II studies, we will decide what the most efficient registration strategy is available to the company with XPro1595. We may to have biopharma partners participate in this decision making. We may also seek to be acquired at this stage.



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**Part-the-Cloud Award**

The Company was awarded a $1,000,000 grant, to be paid in tranches (the "PTC Award") from the Alzheimer's Association in connection with the Alzheimer's Association's Part the Cloud initiative, to advance XPro1595, and received an award letter from the Alzheimer's Association on February 22, 2019 detailing the conditions pertaining to the PTC Award (the "Award Letter"). Pursuant to the Award Letter, the total amount of the PTC Award is $1,000,000 and bi-annual payments will be aligned with the following milestones outlined in the Award Letter: (i) $600,000 on June 15, 2019 upon regulatory approval for opening clinical trial and enrollment of first patient; (ii) if (i) is met, then $250,000 for the next segment (June 15, 2019 – December 15, 2019) if all patients enrolled in first cohort have reached one-month milestone and enrollment of the first patient in the second cohort and (iii) if (ii) is met, then $150,000 for the next segment (December 15, 2019 – June 15, 2020) if all patients enrolled in the second cohort have reached the one-month milestone and enrollment of the first patient in the third cohort.

**Challenges in the Market for Immunotherapy Products**

**Government Regulation**

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development,

approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

Various regulatory authorities regulate, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the FDA and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a new drug application or NDA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some preclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.





The FDA offers a number of regulatory mechanisms that provide expedited or accelerated approval procedures for selected drugs in the indications on which we are focusing our efforts. These include accelerated approval under Subpart H of the agency's NDA approval regulations, fast track drug development procedures and priority review.

We plan to seek orphan drug designation for INKmune for the treatment of ovarian carcinoma. The United States, European Union and other jurisdictions may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which, in the United States, is generally a disease or condition that affects no more than 200,000 individuals. In the European Union, orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than 50 in 100,000 persons in the European Union; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the United States and 10 years in the European Union Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. Orphan drug designation must be requested before submitting an NDA. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. However, this designation provides an exemption from marketing and authorization (NDA) fees. We plan to follow a similar path with INB03, although the precise indication cannot be determined until we are farther along in the development process.

*Clinical Trials*

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.





Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Regulatory procedures differ in each country we will be working in., For example, in the US, each protocol is submitted, to the FDA as part of the IND for their review and consent before enrolling patients in the clinical

trial. The US is not the only place to perform clinical trials. Most countries have systems in place to allow academics and companies to sponsor clinical trials of novel therapies in patients. For financial and technical reasons, the Company will perform the Phase I clinical trials of our programs in the United Kingdom and Australia. The US will be included in the Phase II programs. Other venues such as Europe, Canada, Japan and other Pacific Rim countries may be included in the development program in the future. The first clinical trial with INKmune will be initiated in the United Kingdom. In the United Kingdom, the regulatory submission is made to the MHRA for a clinical trials authorization ("CTA"). This is a multistep process. The Company had a Scientific Advice meeting with the MHRA in September 2017 to discuss the INKmune Phase I/II trial in women with relapse/refractory ovarian cancer including trial design, manufacturing processes and clinical trial execution. The MHRA gave recommendations on trial design, manufacturing controls and the regulatory procedures needed to initiate the clinical trial. We expect to file at CTA for the INKmune trial in ovarian cancer by the third quarter of 2018 and received approval from the MHRA on December 18, 2018. The approval allows for the execution of the Phase I/II INKmune clinical trial in the United Kingdom. We plan to have two cancer clinics referring the 6 patients needed for the Phase I portion of the trial. The patients will be treated at the Phase I unit a university hospital. We expect all of the Phase I sites to be in London, United Kingdom. If the Phase I trial proceeds as planned, we expect to open the Phase II portion of the trial in early 2020. The Phase II trial will include at least 3 other clinical sites in the United Kingdom and may include clinical sites in the US. Because 30 patients will be required to complete the Phase II portion of the trial, we expect to need sites in both the US and United Kingdom. The additional clinical sites in the United Kingdom or US have not been identified at this time. No additional regulatory procedures will be needed to add sites in the United Kingdom. To add sites in the US, we will need to file an IND with the FDA. Once the FDA approves the IND, clinical sites can be opened. We have chosen relapsed/refractory ovarian cancer as the anticipated Phase 1 study for INKmune for a number of reasons. Relapsed refractory is a disease with poor treatment options. Our pre-clinical data suggests INKmune may have advantages over other immunotherapies in the treatment of ovarian cancer. Ovarian cancer has a sensitive and validated biomarker to measure disease burden – CA125. This allows the Company to accurately select patients for the clinical trial and determine if INKmune therapy is effective. We believe that intraperitoneal delivery of INKmune is a low-risk delivery strategy for a phase 1 study. The patients we plan to enroll in the trial have their disease concentrated in the peritoneal cavity further supporting the use of intra-peritoneal delivery. Finally, relapsed refractory ovarian cancer is an Orphan indication in the US. This provides regulatory advantages for registration of INKmune.. INB03 will follow a similar development strategy, but will use Australia for the Phase I programs. In Australia, clinical trials for INB03 are performed under the clinical trials notification ("CTN") scheme authorized by the Therapeutic Good Administration ("TGA"). The TGA is the equivalent agency to the FDA in the US and the MHRA in the United Kingdom. We filed an Australian Clinical Trial Notification, or CTN, for INB03 during the second quarter of 2018. This was accepted in May 2018 to allow us to initiate the Phase I trial. We plan a Phase 1 open label dose escalation trial in patients with advanced solid tumors and biomarkers of inflammation in their blood. We have identified this group of patients as ideal for the INB03 Phase I trial because they will allow the Company to assess safety of INB03 in a relevant patient group and they provide inflammatory biomarkers that allows us to test downstream biologic effects of INB03 therapy. The Phase I trial will provide the evidence of safety and a pharmacodynamic drug affect, decrease of inflammatory biomarkers, needed to move the program to a Phase II clinical trial. If successful, the Phase II clinical trial that will combine INB03 with currently approved checkpoint inhibitor in patients with elevated biomarkers of inflammation in their blood. This is a combination trial where the addition of INB03 to checkpoint inhibitor therapy may improve the efficacy and safety of checkpoint inhibitor therapy alone. Checkpoint inhibitors are immunotherapy drugs that target proteins in the tumor and immune cells to improve the adaptive immune response to the tumor by reversing immunologic strategies the cancer uses to evade the immune system. These drugs target PD1, PDL-1 or CTLA-4. As of April 2018, there are six checkpoint inhibitors approved in the US (Ipilimumab, Atezolizumab, Avelumab, Durvalumab, Pembrolizumab, and Nivolumab). Additional checkpoint inhibitors to new and existing targets are in development and will be approved in the coming years. Checkpoint inhibitors are having a significant impact on the treatment of cancer and are expected to be the largest selling class of cancer therapies by 2027. Only 25-30% of patients treated with currently approved checkpoint inhibitors respond to therapy and many of these become refractory after a period of treatment. This means at least 70% of patients are resistant to, or refractory to, checkpoint inhibitors. Experts agree that combination therapy is needed and necessary to improve the response to checkpoint inhibitor therapy in resistant and refractory patients. To that end, companies with approved checkpoint inhibitors are looking for companion drugs improve patient response and expand market opportunities. The INB03 development program in cancer is designed to take advantage of our pre-clinical data and the needs to the cancer community to improve the safety and efficacy of checkpoint inhibitors. At this time, the combination trial is our lead registration strategy for INB03 for three reasons. The most common biomarker of checkpoint inhibitor failure is increased MDSC in the patient's blood. Pre-clinical data suggests, and experts agree, that decreasing MDSC may improve the response rate to checkpoint inhibitors. Because INB03 decreases number and function of MDSC, we believe combination therapy with INB03 and a checkpoint inhibitor will improve patient responses and allow some refractory or resistant patients to respond to checkpoint inhibitor therapy. Using INB03 in combination with currently approved checkpoint inhibitors is a partnering strategy. We call the class of drugs to be combined with checkpoint inhibitors to improve response in resistant/refractory patients checkpoint inhibitor potentiators. We believe INB03 is an ideal checkpoint inhibitor potentiator and have designed our development program to showcase this characteristic. Checkpoint inhibitor companies announced large partnering deal with companies producing checkpoint inhibitor potentiators – BMS/Nektar; BMS/IFM and Merck/Incyte. Experts agree that partnering in this arena will continue. The registration and development strategy for INB03 is multinational. The Phase II program may enroll patients in other countries, including the United States after submitting an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA. If partnering is successful at any stage of INB03 development, we expect the partner to influence the development and regulatory decisions needed with moving the drug to commercialization. Finally, combination therapy with checkpoint inhibitors is not the only oncology application for INB03. INB03 can be combined with other immune-oncology therapy to improve efficacy, safety or both. INB03 as monotherapy or as an immuno-oncology drug paired with tradition therapies such as chemotherapy or radiation are attractive in certain tumor types. The company is pursuing pre-clinical data in both of these areas. When and if positive developments occur, we will communicate them to our shareholders. There are other regulatory venues that will be important for both our products – the largest and most important is Europe. In Europe, the European Medicines Agencies ("EMA") is responsible for authorization of clinical trials in member states. In EU, there may be a requirement to get individual country authorization at the same time as EMA authorization. The development of INB03 will primarily in AUS followed by trials in the US. The development of INKmune will occur primarily in the United Kingdom followed by trials in the US. XPro1595 is being developed for the treatment of Alzheimer's disease under a Part-the-Cloud Award received Feb 2019. The biomarker directed Phase I trial will be performed in AUS using a regulatory strategy identical to that used for INB03 in cancer. Regulatory approval to initiate the trial was received on February 8, 2019. The clinical trial will be performed at five sites in AUS. XPro1595 treats microglial activation and innate immune dysregulation may be the cause with Alzheimer's disease in some patients. To our knowledge, there are few companies using an anti-inflammatory strategy for the treatment of Alzheimer's disease. Those companies include Denali Therapeutics (NASDAQ: DNLI); developing DNL747 that targets critical signaling proteins in the TNF pathway that regulate inflammation and cell death. Alector (NASDAQ: ALEC) in partnership with Abbvie is developing AL002 that targets TREM2 on microglial cells. Gliacure is targeting microglial cells in Alzheimer's disease with a small molecule candidate GC021109.



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Clinical testing must satisfy extensive FDA regulations. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early stage clinical trials does not assure success in later stage clinical trials. The FDA, an IRB or we may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

*New Drug Applications*

Assuming successful completion of the required clinical trials, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the

product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.



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*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, 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, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Pharmaceutical 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 GMP, 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. If our future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the product.

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.

The FDA closely regulates the marketing, labeling, advertising and promotion of pharmaceutical products. 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. 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.

***Other Healthcare Laws and Compliance Requirements***

Our sales, promotion, medical education, clinical research and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the federal Anti-Kickback Statute, the civil False Claims Act, physician payment transparency laws, privacy laws, security laws, and additional federal and state laws similar to the foregoing.



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The federal Anti-Kickback Statute prohibits, among other things, the knowing and willing, direct or indirect offer, receipt, solicitation or payment of remuneration in exchange for or to induce the referral of patients, including the purchase, order or lease of any good, facility, item or service that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that 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 False Claims Act. Many states have similar laws that apply to their state health care programs as well as private payors.

Federal false claims and false statement laws, including the federal civil False Claims Act, or FCA, imposes liability on persons or entities that, among other things, knowingly present or cause to be presented claims that are false or fraudulent or not provided as claimed for payment or approval by a federal health care program. The FCA has been used to prosecute persons or entities that "cause" the submission of

claims for payment that are inaccurate or fraudulent, by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, submitting claims for services not provided as claimed, or submitting claims for services that were provided but not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multibillion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, certain companies that were found to be in violation of the FCA have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; knowingly and willfully falsifying, concealing or covering up 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; and willfully obstructing a criminal investigation of a healthcare offense. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Given the significant size of actual and potential settlements, we expect that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our products, once commercialized, are sold in a foreign country, we may be subject to similar foreign laws.





In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers are required to collect and report detailed payment data and submit legal attestation to the accuracy of such data to the government each year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Additionally, entities that do not comply with mandatory reporting requirements may be subject to a corporate integrity agreement. Certain states also mandate implementation of commercial compliance programs, impose restrictions on covered manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, imposes specified requirements on certain health care providers, plans and clearinghouses (collectively, "covered entities") and their "business associates," relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain states have their own laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other and/or HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

*Coverage and Reimbursement*

Sales of pharmaceutical products depend significantly on the extent to which coverage and adequate reimbursement are provided by third-party payors. Third-party payors include state and federal government health care programs, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, we cannot be certain of this. Third-party payors are increasingly challenging the price, examining the cost-effectiveness, and reducing reimbursement for medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors, as each payor will make its own determination as to whether to cover a product and at what level of reimbursement. Thus, one payor's decision to provide coverage and adequate reimbursement for a product does not assure that another payor will provide coverage or that the reimbursement levels will be adequate. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.





*Healthcare Reform*

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. 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.

By way of example, in March 2010, the Affordable Care Act was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the

healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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 new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's 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 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include, among others, the Budget Control Act of 2011, which mandates aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.



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We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded 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 drugs.

**Employees**

As of March 25, 2019, we have [three] full-time employees, consisting of our executive officers, and retain the services of additional personnel on an independent contractor basis. We do not have any part-time employees but work with several consultants.

**Item 1a. Risk Factors**

*You should carefully consider the risks described below as well as other information provided to you in this document, including information in the section of this document entitled "Information Regarding Forward Looking Statements." If any of the following risks actually occur, the Company's business, financial condition or results of operations could be materially adversely affected, the value of the Company's Common Stock could decline, and you may lose all or part of your investment.*

**RISKS RELATED TO OUR BUSINESS**

***We have no approved products on the market and have generated no product revenues to date.***

To date, we have no approved products on the market and have generated no product revenues. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of the offering, cash on hand, licensing fees and grants and additional financings, to the extent such financings can be obtained.

***We will need additional capital. If additional capital is not available or is available at unattractive terms, we may be forced to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations.***

In order to develop and bring our product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical and clinical trials and marketing activities. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations for at least the next twelve months. We anticipate using our cash and cash equivalents to fund further research and development with respect to our lead product candidates. We may, however, need to raise additional funding sooner if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. Our requirements for additional capital will depend on many factors, including:

- successful commercialization of our product candidates;
- the time and costs involved in obtaining regulatory approval for our product candidates;
- costs associated with protecting our intellectual property rights;
- development of marketing and sales capabilities;
- payments received under future collaborative agreements, if any; and
- market acceptance of our products, if any.

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To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our shareholders. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

The Company will require substantial additional funds to support its research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization. Such additional sources of financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to initiate clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders.

***There is doubt about our ability to continue as a going concern.***

As of December 31, 2018, the Company had an accumulated deficit of $13,597,868. Losses have principally occurred as a result of the substantial resources required for research and development of the Company's product candidates which included the general and administrative expenses associated with its organization and product development as well as the lack of sources of revenues until such time as the Company's products are commercialized. These factors raise substantial doubt about the Company's ability to continue as a going concern from the issuance date of these financial statements. These financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of these uncertainties. Management intends to pursue additional funding and implement its strategic plan to allow the opportunity for the Company to continue as a going concern, however, there cannot be any assurance that we will be successful in doing so.

There is no assurance that we will be successful in raising the additional funds needed to fund our business plan. If we are not able to raise sufficient capital in the near future, our continued operations will be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

***We face intense competition in the markets targeted by our lead product candidates. Many of our competitors have substantially greater resources than we do, and we expect that all of our product candidates under development will face intense competition from existing or future drugs.***

We expect that all of our product candidates under development, if approved, will face intense competition from existing and future drugs marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify drug candidates or develop products earlier than we do, or develop products that are more effective, have fewer side effects or cost less than our products, if any.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See "Business — Government Regulation."

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.



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***Competition and technological change may make our product candidates and technologies less attractive or obsolete.***

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

***The clinical and commercial utility of our INKmune therapy is uncertain and may never be realized.***

Our INKmune therapy is in an early stage of development. We received approval by the MHRA to start Phase a Phase I/II trial on December 18, 2018. Success in early clinical trials, if achieved, does not ensure that large-scale trials will be successful, nor does it predict final results.

We may not ultimately be able to provide the FDA with satisfactory data to support a claim of clinical safety and efficacy sufficient to enable the FDA to approve INKmune for commercialization. This may be because clinical trials may fail to produce favorable data, because the FDA may disagree with how we interpret the data from these clinical trials, or because the FDA may not accept these therapeutic effects as valid endpoints in pivotal trials necessary for market approval. We will also need to demonstrate that INKmune therapy is safe. We do not have data on possible harmful long-term effects of INKmune therapy and will not have any data on long-term effects in the near future. For these and

other reasons, the clinical effectiveness and commercialization of INKmune therapy is uncertain and may never be realized.

***If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected.***

Our success will depend, in part, on our ability to obtain patents and maintain adequate protection of our technologies and products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies to produce and market drugs in direct competition with us and erode our competitive advantage. Some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in these foreign countries. We may not be able to prevent misappropriation of our proprietary rights.



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We have received, and are currently seeking, patent protection for numerous compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following: patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage; our competitors, many of which have substantially greater resources than us and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets; there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

Moreover, any patents issued to us may not provide us with meaningful protection, or others may challenge, circumvent or narrow our patents. Third parties may also independently develop products similar to our products, duplicate our unpatented products or design around any patents on products we develop. Additionally, extensive time is required for development, testing and regulatory review of a potential product. While extensions of patent term due to regulatory delays may be available, it is possible that, before any of our product candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent.

In addition, the United States Patent and Trademark Office (the "USPTO") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

Our success depends on patent applications that are licensed exclusively to us and other patents to which we may obtain assignment or licenses. We may not be aware, however, of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our product candidates to us or our licensors, or by covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have.

Patent protection and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

***We license our patents from third party owners. If such owners do not properly maintain or enforce the intellectual property underlying such licenses, our competitive position and business prospects could be harmed. Our licensors may also seek to terminate our license.***

We are a party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful to our business. To this end, we are dependent on our licenses with Xencor, Inc., Immune Ventures, LLC and the University of Pittsburgh. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce our licensed intellectual property. Our licensors may not successfully prosecute any applications for or maintain intellectual property to which we have licenses, may determine not to pursue litigation against other companies that are infringing such intellectual property, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer similar products for sale, which could adversely affect our competitive business position and harm our business prospects. If we lose any of our right to use third-party intellectual property, it could adversely affect our ability to commercialize our technologies, products or services, as well as harm our competitive business position and our business prospects.



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***We are dependent on our licensing agreement with Xencor and the termination of this agreement could a have an adverse effect on our business.***

On October 3, 2017, the Company entered into a license agreement with Xencor, Inc., which has discovered and developed a proprietary biological molecule that inhibits soluble tumor necrosis factor. Pursuant to the license agreement, Xencor granted the Company an exclusive worldwide, royalty-bearing license in licensed patent rights, licensed know-how and licensed materials to make, develop, use, sell and import any pharmaceutical product that comprises, contains, or incorporates Xencor's proprietary protein known as "XPRO1595" that inhibits soluble tumor necrosis factor (or all modifications, formulations and variants of the licensed protein that specifically bind soluble tumor necrosis factor) alone or in combination with one or more active ingredients, in any dosage or formulation. If we breach this Agreement Xencor may be able to terminate it and as a result of this terminate our business could be negatively impacted.

***Our officers and Directors own the company that we license our principal patent from.***

On October 29, 2015, we entered into an exclusive license agreement with Immune Ventures, LLC, the owner of all of the rights related to our principal patent. The license agreement relates to our natural killer program, INKmue. Immune Ventures is owned by our President and a member of our Board of Directors, David Moss, our Chief Financial Officer and Treasurer and Mark Lowdell, our Chief Scientific Officer. Because our officers and directors also own Immune Ventures there may be an inherent conflict of interest which could result in unanticipated

actions that adversely affect us.

***We have a limited operating history, and expect to incur significant additional operating losses.***

We are an early stage company formed in September 2015 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We expect to incur substantial additional operating expenses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the preclinical and clinical development of our product candidate; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; implementing successful manufacturing, sales, and marketing arrangements; and raising sufficient funds to finance our activities. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

***INKmune represents a novel approach to cancer treatment that creates significant challenges for us.***

We believe INKmune represents a novel approach to cancer treatment. Advancing this novel therapy creates significant challenges for us, including:

- Educating medical personnel regarding the potential side effect profile of INKmune;
- Sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- Obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of immunotherapies for cancer; and
- Establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.



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***Even if we are able to commercialize any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.***

The commercial success of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as Medicare and Medicaid), private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on our investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

***We depend on obtaining certain patents and protecting our proprietary rights.***

Our success will depend, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties or having third parties circumvent our rights. We have filed and are actively pursuing a patent application for our product candidates. The patent positions of biotechnology, biopharmaceutical and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Thus, there can be no assurance that our patent application will result in the issuance of a patent, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with any competitive advantages or will not be challenged by any third parties, that the patents of others will not impede our ability to do business or that third parties will not be able to circumvent our patents. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of our products not under patent protection, or, if patents are issued to us, design around the patented products we developed or will develop.

We may be required to obtain licenses from third parties to avoid infringing patents or other proprietary rights. No assurance can be given that any licenses required under any such patents or proprietary rights would be made available, if at all, on terms we find acceptable. If we do not obtain such licenses, we could encounter delays in the introduction of products or could find that the development, manufacture or sale of products requiring such licenses could be prohibited.

A number of pharmaceutical, biopharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of our patent applications. In addition, if patents that cover our activities are issued to other companies, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology. If we do not obtain such licenses, we could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited. In addition, we could incur substantial costs in defending ourselves in suits brought against us on patents it might infringe or in filing suits against others to have such patents declared invalid.



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Much of our know-how and technology may not be patentable. To protect our rights, we plan to require employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, our business may be adversely affected by competitors who independently develop competing technologies, especially if we obtain no, or only narrow, patent protection.

***We are subject to various government regulations.***

The manufacture and sale of human therapeutic products in the U.S. and foreign jurisdictions are governed by a variety of statutes and regulations. These laws require approval of manufacturing facilities, controlled research and testing of products and government review and approval of a submission containing manufacturing, preclinical and clinical data in order to obtain marketing approval based on establishing the safety and efficacy of the product for each use sought, including adherence to current cGMP during production and storage, and control of marketing activities, including advertising and labeling.

The products we are currently developing will require significant development, preclinical and clinical testing and investment of substantial funds prior to its commercialization. The process of obtaining required approvals can be costly and time-consuming, and there can be no assurance that we develop successfully this product or any future products, or that this product or any future products we develop will prove to be safe and effective in clinical trials or receive applicable regulatory approvals. Potential investors and shareholders should be aware of the risks, problems, delays, expenses and difficulties which we may encounter in view of the extensive regulatory environment which controls our business.

***If we are unable to keep up with rapid technological changes in our field or compete effectively, we will be unable to operate profitably.***

We are engaged in a rapidly changing field. Other products and therapies that will compete directly with the product that we are seeking to develop and market currently exist or are being developed. Competition from fully integrated pharmaceutical companies and more established biotechnology companies is intense and is expected to increase. Most of these companies have significantly greater financial resources and expertise in discovery and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than us. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biopharmaceutical or biotechnology companies. Many of these competitors have significant products that have been approved or are in development and operate large, well-funded discovery and development programs. Academic institutions, governmental agencies and other public and private research organizations also conduct research, seek patent protection and establish collaborative arrangements for therapeutic products and clinical development and marketing. These companies and institutions compete with us in recruiting and retaining highly qualified scientific and management personnel. In addition to the above factors, we will face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, price and patent position. There is no assurance that our competitors will not develop more effective or more affordable products, or achieve earlier patent protection or product commercialization, than our own.

Other companies may succeed in developing products earlier than ourselves, obtaining FDA and European Medicines Agency ("EMA") approvals for such products more rapidly than we will, or in developing products that are more effective than products we propose to develop. While we will seek to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop, or that any therapy we develop will be preferred to any existing or newly developed technologies.



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***We may request priority review for our product candidate in the future. The FDA may not grant priority review for our product candidate. Moreover, even if the FDA designates such product for priority review, that designation may not lead to a faster regulatory review or approval process and, in any event, would not assure FDA approval.***

We may be eligible for priority review designation for our product candidate if the FDA determines such product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists. A priority review designation means that the goal for the FDA to review an application in six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Thus, while the FDA has granted priority review to other oncology disease products, our product candidate, should we determine to seek priority review, may not receive similar designation. Moreover, even if our product candidate is designated for priority review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within an accelerated timeline or thereafter.

***We believe we may in some instances be able to secure approval from the FDA or comparable non-U.S. regulatory authorities to use accelerated development pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.***

We anticipate that we may seek an accelerated approval pathway for our product candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a New Drug Application, or NDA, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other non-U.S. authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization of our product candidate.***

Our product candidates have not entered into clinical trials and are in development stage. Therefore, the risk of failure of our product candidates is high. It is impossible to predict when or if our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, 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. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable non-U.S. regulatory authority that a drug product is not safe or effective for its intended uses. It is possible that even if our product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face additional setbacks.

The design of a clinical trial can determine whether its results will support approval of a product; however, flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidate warrant marketing approval, the FDA or comparable non-U.S. regulatory authorities may disagree and may not grant marketing approval of our product candidate.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidate.

***If clinical trials of our product candidate fail to demonstrate safety and efficacy to the satisfaction of the FDA and comparable non-U.S. regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable non-U.S. regulatory authorities, such as the EMA, impose similar restrictions. We may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidate in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable non-U.S. regulatory authorities for any product candidate.





Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if (1) we are required to conduct additional clinical trials or other testing of our product candidate beyond the trials and testing than we contemplate, (2) we are unable to successfully complete clinical trials of our product candidate or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidate, we, in addition to incurring additional costs, may:

- be delayed in obtaining marketing approval for our product candidate;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as we intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

***If we experience any of a number of possible unforeseen events in connection with clinical trials of any of our product candidates, potential marketing approval or commercialization of that product candidate could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval of any of our product candidates, including:

- clinical trials of our product candidate may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidate may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- data safety monitoring committees may recommend suspension, termination or a clinical hold for various reasons, including

concerns about patient safety;

- regulators or institutional review boards, or IRBs, may suspend or terminate the trial or impose a clinical hold for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- patients with serious, life-threatening diseases included in our clinical trials may die or suffer other adverse medical events for reasons that may not be related to our product candidate;
- participating patients may be subject to unacceptable health risks;
- patients may not complete clinical trials due to safety issues, side effects, or other reasons;
- changes in regulatory requirements and guidance may occur, which require us to amend clinical trial protocols to reflect these changes;
- our third-party contractors, including those manufacturing our product candidate or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;





- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we may have to suspend or terminate clinical trials of our product candidate for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of a product candidate;
- the FDA or comparable non-U.S. regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable non-U.S. regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidate or other materials necessary to conduct clinical trials of our product candidate may be insufficient, inadequate, delayed, or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of our product candidates.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, we may not achieve our clinical development on our anticipated timeline, or at all, and our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for INKmune or any other product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.





Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to achieve our

clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from our product candidates. Any of the foregoing could cause the value of the Company to decline and limit our ability to obtain additional financing, if needed.

***We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.***

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the USPTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

***We may rely on orphan drug status to develop and commercialize our product candidates, but orphan drug designation, if obtained, may not confer marketing exclusivity or other expected commercial benefits as anticipated.***

Market exclusivity afforded by orphan drug designation is generally offered as an incentive to drug developers to invest in developing and commercializing products for unique diseases that impact a limited number of patients. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Qualification to maintain orphan drug status is generally monitored by the regulatory authorities during the orphan drug exclusivity period, currently seven years from the date of approval in the United States.

We intend to seek orphan drug designation in the United States for our product candidate for the treatment of AML and ovarian cancer and we expect to rely on orphan drug exclusivity for our product candidate. Even if granted, orphan drug designation, and related market exclusivity, in the United States could be lost. Further, even if we are granted orphan drug status, the FDA can still approve different drugs for use in treating the same indication or disease, which would create a more competitive market for us and our revenues will be diminished.



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Further, for our product candidate, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

***If the market opportunities for our product candidate are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidate are small, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.***

We focus our research and product development on treatments for certain cancer indications. Our projections of both the number of people who have failed other therapies or have limited medical options for such indications, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence. The number of patients with such diseases in the United States, Europe and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

***We may fail to comply with regulatory requirements.***

Our success will be dependent upon our ability, and our collaborative partners' abilities, to maintain compliance with regulatory requirements, including cGMP, and safety reporting obligations. The failure to comply with applicable regulatory requirements can result in, among other things, fines, injunctions, civil penalties, total or partial suspension of regulatory approvals, refusal to approve pending applications, recalls or seizures of products, operating and production restrictions and criminal prosecutions.

***Even if our product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we estimate.***

We have never commercialized a product. Even if INKmune, INB03 or any other product candidate we develop is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidate may require significant resources and may not be successful. If our product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of INmune or any other product candidate we develop, if approved for commercial sale, will depend on a number of factors, including:



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- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments;

- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability to offer the product for sale at competitive prices;
- our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products and other therapies;
- availability and amount of reimbursement from government payors, managed care plans and other third-party payors;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for our product candidate are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidate could be smaller than our estimates of the potential market opportunities.

***Even if we obtain regulatory approvals for INKmune and/or INB03, those approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could prevent us from realizing the full benefit of our efforts.***

If we obtain regulatory approvals, INKmune and/or INB03 therapy, and the manufacturing facilities used for its production will be subject to continual review, including periodic inspections, by the FDA and other United States and foreign regulatory authorities. In addition, regulatory authorities may impose significant restrictions on the indicated uses or marketing of INKmune or other products that we may develop. These and other factors may significantly restrict our ability to successfully commercialize INKmune.

We and many of our vendors and suppliers will be required to comply with current Good Manufacturing Practices, or GMP, which include requirements relating to quality control and quality assurance as well as to the corresponding maintenance of records and documentation. Furthermore, any manufacturing facilities will need to be approved by regulatory agencies before these facilities can be used to manufacture INKmune, and they will also be subject to additional regulatory inspections. Any material changes we may make to our manufacturing process may require approval by the FDA and state or foreign regulatory authorities. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.



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We must also report adverse events that occur when our products are used. The discovery of previously unknown problems with INKMune, INB03 or manufacturing facilities used to manufacture INKmune or INB03 may result in restrictions or sanctions on our products or manufacturing facilities, including withdrawal of our products from the market. Regulatory agencies may also require us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our product or obtain re-approvals. This may cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

***If our product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.***

Clinical trials of our product candidate will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of our product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we may be required to recall the drug or change the way the drug is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business.

***Any product candidate for which we obtain marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities.***

These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, good manufacturing practices, or GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of our product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling.

In addition, later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- requirements to institute a risk evaluation mitigation strategy, or REMS, to monitor safety of the product post-approval;
- warning letters issued by the FDA or other regulatory authorities;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products, fines, restitution or disgorgement of profits or revenue;
- suspension, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing products. If we develop internal sales, marketing and distribution organization, this would require significant capital expenditures, management resources and time, and we would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we expect to pursue collaborative arrangements regarding the sales, marketing and distribution of our products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, their sales forces may not be successful in marketing our products. Any revenue we receive would depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the sales, marketing and distribution efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales, marketing and distribution efforts of our product candidates. There can be no assurance that we will be able to develop internal sales, marketing distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.



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***We face substantial competition from other pharmaceutical and biotechnology companies and our operating results may suffer if we fail to compete effectively.***

The development and commercialization of new drug products is highly competitive. We expect that we will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to INKmune and any other of our product candidates that we may seek to develop or commercialize in the future. Specifically, due to the large unmet medical need, global demographics and relatively attractive reimbursement dynamics, the oncology market is fiercely competitive and there are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects or are less costly than any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

***We rely on key personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to grow effectively.***

We are dependent on certain members of our management, the loss of services of one or more of whom could materially adversely affect us. In particular, our success depends to a significant extent upon the continued services of Dr. Raymond J. Tesi, our President and CEO. Dr. Tesi has overseen INmune Bio since inception and provides leadership for our growth and operations strategy as well as being an inventor of our patents. Although we have entered into an employment agreement with Dr. Tesi, if he were to nevertheless terminate his employment with us, the loss of the services of Dr. Tesi, would have a material adverse effect on our growth, revenues, and prospective business. We are also highly dependent on the other principal members of our management and scientific team. We are not aware of any present intention of any of our key personnel to leave our company or to retire. The loss of any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations.

Our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit

and train new employees. There can be no assurance that we will be able to successfully attract and retain skilled and experienced personnel.

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.***

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidate despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we commercially sell any product that we may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical 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 or a breach of warranties. 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 product candidate. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidate or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.





Although we plan to maintain general liability insurance, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

***We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.***

To execute our business plan, we will need to rapidly add other management, accounting, regulatory, manufacturing and scientific staff. We currently have 3 full time employees consisting of our executive officers and retain the services of additional personnel on an independent contractor basis. We will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and manufacturing departments as we expand our clinical trial and research capabilities. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

***If we or any of our third-party manufacturers do not maintain high standards of manufacturing, our ability to develop and commercialize our product candidate could be delayed or curtailed.***

We and any third parties that we may use in the future to manufacture our products must continuously adhere to cGMP regulations rigorously enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third parties who produce our products do not pass a pre-approval inspection, the FDA will not grant market approval for INKmune. In complying with cGMP, we and any third-party manufacturers will need to expend significant time, money and effort in production, record-keeping and quality control to assure that each component of INKmune meets applicable specifications and other requirements. We or any of these third-party manufacturers may also be subject to comparable or more stringent regulations of foreign regulatory authorities. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action, which could delay or curtail our ability to develop, obtain regulatory approval of, and commercialize INKmune. If our component part manufacturers and suppliers fail to provide components of sufficient quality, and that meet our required specifications, our clinical trials or commercialization of INKmune could be delayed or halted, and we could face product liability claims.

***If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and any third-party manufacturers. We and such manufacturers will be subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we will seek to ensure that our procedures for using, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.





***We plan to rely on third parties to conduct clinical trials for our product candidate. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidate may delay or impair our ability to obtain regulatory approval for our product candidate.***

We plan to rely on academic institutions and private oncology centers to conduct and sponsor clinical trials relating to INKmune. Our reliance on third parties to conduct clinical trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities.

Such clinical trial arrangements will provide us with information rights with respect to the clinical data, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the clinical trials. If investigators or institutions breach their obligations with respect to the clinical trials of our product candidate, or if the data proves to be inadequate, then our ability to design and conduct any future clinical trials may be adversely affected.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will design our clinical trials and will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidate and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidate.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidate or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***Recent legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our products, if approved, could materially affect our opportunity to commercialize such products.***

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, if approved. 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 to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:





- the demand for any of our products, if approved;
- our ability to set a price that we believe is fair for any of our products, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In March 2010, the Affordable Care Act, or the ACA, became law in the United States (see "Business — Government Regulation"). The goal of ACA is to reduce the cost of healthcare, broaden access to health insurance, constrain healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry, impose additional health policy reforms, and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of any of our products, if they are approved.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened 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.

In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent application, which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of

the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications.



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Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

***The United Kingdom's vote in favor of withdrawing from the European Union could lead to increased market volatility which could make it more difficult for us to do business in the U.K. or have other adverse effects on our business.***

The U.K. is currently negotiating the terms of its exit from the European Union ("Brexit") scheduled for March 29, 2019. In November 2018, the U.K. and the European Union agreed upon a draft withdrawal agreement ("Withdrawal Agreement") that sets out the terms of the U.K.'s departure, including commitments on citizen rights after Brexit, a financial settlement from the U.K., and a transition period from March 29, 2019 through December 31, 2020 to allow time for a future trade agreement to be agreed. On January 15, 2019, the draft Withdrawal Agreement was rejected by the U.K. Parliament creating significant uncertainty about the terms (and timing) under which the U.K. will leave the European Union. If no agreement can be reached and the U.K. leaves the European Union with no agreement ("hard Brexit"), there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our financial results. Further this could change or eliminate the R&D rebate program that the company uses to help fund R&D and clinical trials.

**Risks Related to our Common Stock**

***The Company's common stock is controlled by insiders.***

The Company's officers and directors beneficially own 72.86% of our outstanding common stock. Accordingly, shareholders may have no effective voice in the management of the Company.

***We do not intend to pay dividends for the foreseeable future.***

We have paid no dividends on our common stock to date, and we do not anticipate paying any dividends to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, we anticipate that we will retain any earnings to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our common stock, and could significantly affect the value of any investment in our Company.

***Our articles of incorporation allow for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.***

Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.



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***We are subject to the reporting requirements of federal securities laws, which can be expensive and may divert resources from other projects, thus impairing our ability grow.***

We are a public reporting company and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders would cause our expenses to be higher than they would be if we remained privately held.

It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures.

***We have elected to take advantage of specified reduced disclosure requirements applicable to an "emerging growth company" under the JOBS Act, the information that we provide to stockholders may be different than they might receive from other public companies.***

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" under the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non- binding advisory votes on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting and delaying the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies.

We have elected to take advantage of the above-referenced exemptions and we may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenues, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We have not taken advantage of any of these reduced reporting burdens in this Annual Report, although we may choose to do so in future filings. If we do, the information that we provide stockholders may be different than you might get from other public companies that comply with public company effective dates.



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***Our stock price may be volatile.***

The market price of our Common Stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- regulatory developments;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- inability to develop or acquire new or needed technology or products.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our Common Stock.

***You may have difficulty trading and obtaining quotations for our Common Stock.***

Our securities are not actively traded, and the bid and asked prices for our Common Stock may fluctuate widely. As a result, investors may find it difficult to dispose of, or to obtain accurate quotations of the price of, our securities. This severely limits the liquidity of the Common Stock, and would likely reduce the market price of our Common Stock and hamper our ability to raise additional capital. There is a limited market for our securities. Accordingly, investors may therefore bear the economic risk of an investment in the Securities thereof, for an indefinite period of time.

***Additional stock offerings in the future may dilute your percentage ownership of our company.***

Given our plans and expectations that we may need additional capital and personnel, we may need to issue additional shares of common stock or securities convertible or exercisable for shares of common stock, including convertible preferred stock, convertible notes, stock options or warrants. The issuance of additional securities in the future will dilute the percentage ownership of then current stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

None.

**ITEM 3. LEGAL PROCEEDINGS**

There are no legal proceedings to which we are a party to or which ay of our property is subject.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



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**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Common Stock**

Our common stock began trading on the Nasdaq under the symbol "INMB" on February 4, 2019. Prior to that, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years or provided a performance graph.

As of March 25, 2019, there were 9,740,261 shares of our common stock outstanding held by approximately 63 holders of record.

**Sales of Unregistered Securities**

On May 16, 2018, the Company entered into a consulting agreement with Pacific Seaboard Investments Ltd. for corporate governance, compliance services regarding the filing of a listing application and assist with activities related to its initial public offering. The term of the consulting agreement is from April 24, 2018 to May 1, 2021. In consideration of the consultant's services, the Company agreed to issue 600,000 shares of its restricted common stock, of which 200,000 shares were to be issued on May 16, 2018 (these shares are not yet issued as of December 31, 2018), 200,000 shares shall be locked up for six months after the effective date of the Company's registration statement and 200,000 shares shall be locked up for 10 months after the date of the Company's offering. Pursuant to this agreement, the Company recorded $4,626,000 of stock-based compensation expense during the year ended December 31, 2018 for the 600,000 shares of common stock to be issued.

During the year ended December 31, 2018, to complete a series of funding provided for in the Company's joint development agreement dated September 3, 2016, the Company received $900,000 in cash from Luminus in exchange for 400,000 shares of the Company's common stock. Luminus is owned by a significant shareholder of the Company.

In connection with the foregoing, we relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

**Purchases of Equity Securities by the Issuer**

There were no repurchases of our common stock during the year ended December 31, 2018.



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**Equity Compensation Plan Information**

As of December 31, 2018, all compensation based on our equity was awarded under the INmune Bio, Inc. 2017 Stock Incentive Plan (the "2017 Plan"). The 2017 Plan provides for the grant of stock awards to employees, directors and consultants of the Company and its affiliates covering an aggregate of 1,700,000 shares of common stock, subject to adjustments in the event of certain changes to the Company's capitalization. The awards made under the plan as of December 31, 2018, are set out below:

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | 1,632,000 | $ 7.80 | 68,000 |
| Equity compensation plans not approved by security holders | | | |
| Total | 1,632,000 | $ 7.80 | 68,000 |

**Dividend Policy**

We have not declared any cash dividends on our common stock since inception and do not anticipate paying such dividends in the foreseeable future. We plan to retain any future earnings for use in our business operations. Any decisions as to future payment of cash dividends will depend on our earnings and financial position and such other factors as the Board of Directors deems relevant.

**Item 6. Selected Financial Data**

As a smaller reporting company, as defined in Rule 12b-2 promulgated under the Exchange Act, and in Item 10(f)91) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information required by this item.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and notes thereto appearing elsewhere in this Annual Report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those anticipated by these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Form 10-K, including those set forth under "Risk Factors" and "Forward-Looking Statements."*

**Overview**

We are a clinical-stage immunotherapy company focused on reprograming the patient's innate immune system to treat disease. We do this by targeting three key cells of the innate immune system, natural killer, or NK cells, and myeloid derived suppressor cells, or MDSC and microglial cells of the central nervous system. NK cells are the body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells, such as cancer or virally-infected cells, without prior exposure or activation by other support molecules required to activate adaptive immune cells such as T-cells. NK cells play a key role in the immune-surveillance that prevents people from getting cancer and in

eliminating residual disease which may cause people to relapse after cytotoxic therapy. MDSC are myeloid cells that develop secondary to the chronic inflammatory environment found in many cancers. MDSC, produced in the bone marrow, take up residence in the tumor microenvironment, the tissue associated with the cancerous cells, to protect to the tumor from immunological attack by the patient's immune system. MDSC play a critical role in making the cancer resistant to immunotherapy such as currently approved checkpoint inhibitors. Microglial cells are the primary immune cells of the central nervous system responsible for protecting the neural unit of microglia, astrocytes, oligodendrocytes and neurons from infection. In the setting of chronic inflammation, microglial cells become activated and cause dysfunction of the other three cells types in the neural unit resulting in neurodegenerative and neuropsychiatric diseases. INB03 and XPro1595 are the identical drug used in different therapeutic arenas. INB03 is the name of the drug for cancer targeted applications. XPro1595 in the name of the drug for neurology and psychiatric indications.



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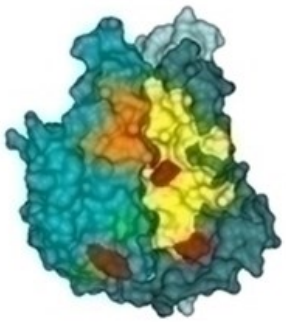
We believe INKmune, our NK cell directed therapy, and INB03 and our MDSC directed therapy our microglial directed offer unique strategies to improve the response of patient's the innate immune system to their cancer. These therapies will use a precision medicine approach to select patients who will benefit from the therapy and monitor the response to the therapy. Neither therapy is cancer specific. The decision to use either INKmune or INB03 alone or in combination other cancer therapies or with each other depends on immunologic parameters that can be tested in patients before treatment. The type of cancer is not important. This means that both therapies can be used to treat patients wide varied to hematologic malignancies and solid tumors that have the immunologic profile needed to respond. Put simply, we are treating the immune system to attack the patients the cancer, not targeting the patient's cancer directly.

Likewise, we believe XPro1595, our microglial directed therapy, offers a unique strategy to decrease neuroinflammation, a key pathophysiology in neurodegenerative and neuropsychiatric diseases. XPro1595 will use a precision medicine approach to select patients who will benefit from the therapy and monitor the response to the therapy. The therapy is not diagnosis specific but will be used in patients who have biomarkers of neuroinflammation. Our initial program with XPro1595 will be treating patients with mild to moderate Alzheimer's disease with biomarkers inflammation.

We believe that INKmune improves the ability of the patient's own NK cells to attack their tumor. INKmune itself will not kill cancer cells. INKmune interacts with the patient's NK cells to convert them from an inert resting NK cells that ignores the cancer into a primed NK cells that kills the cancer cell. INKmune is a replication incompetent proprietary cell line we have named INB16 that is given to the patient after determining that i) the patient has adequate NK cells in their circulation and ii) those NK cells are functional when exposed to INKmune in vitro. INKmune is designed to be given to patients after their immune system has recovered after cytotoxic chemotherapy to target the residual disease the remains after treatment with cytotoxic therapy.

Figure 4: INB03 is a bioengineered 27 kDal protein that is identical to the monomeric subunit that forms the TNF homotrimer. There are 6 amino acid mutations engineered into the protein, 3 are on the surface of the protein (red). Two of the protein mutations are in the binding site to prevent binding to TNF receptor. The third mutation is to allow efficient PEGylation with a linear 10 kDal PEG that improves half-life to 18 hours. The protein is produced in E.coli.



INB03, shown in Figure 4 above, is an engineered protein therapeutic that neutralizes soluble TNF using Dominant-Negative technology. Dominant-Negative TNF biology is possible because of the unique properties of TNF. TNF is comprised of 3 identical proteins that form a homotrimer that bind the TNF receptor. INB03, a mutated form of the monomer, can displace one or more of the monomers for the sTNF homotrimer to form a heterotrimer. The heterotrimer is unable to bind TNFR. Without sTNF/TNFR interaction, there is not biologic affect. This is shown in Figure 5 below.



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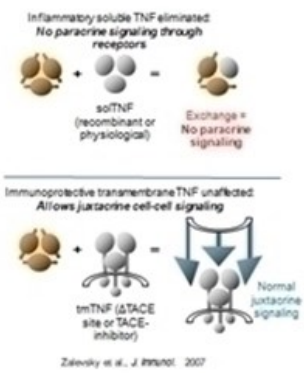
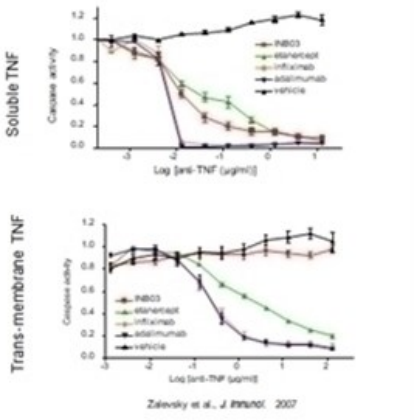
Figure 5: INB03 is a novel dominant-negative TNF inhibitor that is very different from currently approved non-selective TNF inhibitor. TNF is a homo-trimer that binds the TNF receptor. INB03 (brown ovals with handlebars) is a mutated TNF that freely exchanges with soluble TNF (top panel) to form a heterotrimer that can not bind to TNF receptors. INB03 can not effect trans-membrane TNF because the TNF monomers are anchored to the cell membrane (lower panel). The unique mechanism of action allows INB03 to be highly selective inhibitor of soluble TNF. Currently available TNF inhibitors block both soluble and transmembrane TNF. These non-selective TNF inhibitors have an efficacy and safety profile that is different from INB03. Also, soluble TNF can have effects on cells distant from the source of the cytokine. Transmembrane TNF, because it is protein bound requires cell-cell contact to have its effects.




The unique mechanism of action allows INB03 to be the only selective TNF inhibitor that affects only sTNF. All currently available TNF inhibitors are non-selective TNF inhibitors that block both sTNF and tmTNF. This functional difference shown in Figure 6 below translates into therapeutic differences. The most obvious in the use of a TNF inhibitor in the treatment of cancer patients is related to safety. Non-selective TNF inhibitors are immunosuppressive because they inhibit both sTNF and tmTNF. INB03 is not immunosuppressive because it inhibits only

sTNF and allows tmTNF to function normally (please refer to Figure 3). In animal models of cancer, the combination of no sTNF with functional tmTNF after treatment with INB03 improved the immune response against the tumor compared to animals treated with the non-selective TNF inhibitor etanercept (Vujanovic 2016). In summary, sTNF, by binding to TNFR1, is essential for MDSC proliferation by causing phosphorylation of STAT3. Without the binding of sTNF to TNFR1, the proliferation of the MDSC stops and the MDSC population collapses. Without the immunosuppressive shield provided by the MDSC population, the patient's immune system, without concomitant immunotherapy, can attack the tumor. A secondary effect of INB03 is to improve NK cells-dendritic cell (NK/DC) cross-talk to help expand patient's anti-tumor immune response by recruiting cytotoxic T cells of the adaptive immune system. tmTNF is essential to NK/DC cross-talk.

Figure 6: INB03 is a Dominant-Negative TNF inhibitor that block soluble TNF without affecting transmembrane TNF. This gives INB03 a different safety and efficacy profile from existing non-selective TNF inhibitors. The specificity of INB03 comparted to 3 currently approved non-selective TNF inhibitors is shown in the figure. INB03, etanercept, infliximab and adalimumab all inhibit soluble TNF (top figure). INB03 does not inhibit trans-membrane TNF while , etanercept, infliximab and adalimumab do inhibit trans-membrane TNF. The caspase activity assay is a well validated assay to demonstrate TNF function.




We believe our innate immune system reprogram platforms provides unique strategies to repair the immunologic dysfunction that characterizes the innate immune system of patients with cancer. The products can be used alone, in combination with other anti-tumor or immunotherapy treatments or with each other. In the near term, we are developing the products separately. After completion of proof-of-concept Phase II trials, we will consider developing them as a combination therapy. Until we complete clinical trials, we cannot predict if either product will be successful when use alone, in combination with other therapies or in combination with each other.



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The mechanism of action for XPro1595 is identical to INB03, but the cell type targeted in neurodegenerative and neuropsychiatric disease is different. Microglial cells are macrophage like immune cell that is unique to the central nervous system. Activated microglial cells produce inflammatory cytokines and phagocytos debris in the brain to promote normal function of the neural unit and protect the brain against infection. Chronic inflammation is a low grade, unrelenting inflammatory process that is destructive to the host resulting in dendritic pruning, synaptic dysfunction and cell dysfunction and death. Death of nerve cells can cause cognitive decline of AD, motor dysfunction of Parkinson's disease or ALS. Death of oligodendrocytes that produce myelin can cause MS and other demyelinating diseases. In the brain, the unique action of XPro1595 to neutralize the destructive cytokine soluble TNF while promoting the function of the trans-membrane TNF, the protective cytokine is unique. Neutralization of soluble TNF and polarization of the immunology to trans-membrane TNF effects prevents dendritic pruning and synaptic dysfunction, promotes phagocytosis of debris by microglial cells and prevents demyelinization of neurons. These effects have benefits across a broad range of neurodegenerative and neuropsychiatirc diseases. At this time, due to non-dilutive funding provided by the Part-the-Cloud Award from the Alzheimer's Association, we will focus our develop efforts on Alzheimer's disease. The funding provided by the Alzheimer's Association supports a Phase I trial. If the trial is successful and the Company decides to pursue additional development is AD, additional funding will be needed to support a Phase II trial. In the future, when resources become available, we may expand our activities other neurodegenerative or neuropsychiatric diseases.

Mesenchymal Stem Cells ("MSC") are pluripotent cells with potent immunologic effects which can be used alone as an anti-inflammatory treatment strategy or a vector to deliver gene therapy. We have access to a large quantity of human, GMP-grade MSC that can be repurposed for use in medical research or clinical trials. We plan to sell these cells to third parties. We may expand this activity in the future to include positioning the company as a contract manufacturer for companies developing MSC products or developing our own MSC based products. At this time, the program will be self-sustaining and growing on reinvestment of revenues from the sale of the MSC products.

*Our Integrated Discovery and Development Process*. Our focus on reprograming the patient's immune system to better attack disease allows for synergies between the development and discovery process. A majority of our effort is focused on the development process that includes improving the manufacturing systems for INKmune and INB03/XPro1595 and optimizing bioassays to be used during the clinical trials. These manufacturing and monitoring programs may produce discoveries that the company can capitalize on as product improvements or new products. INB03 has uses beyond treatment of resistance to immunotherapy in oncology and XPro1595 has uses beyond the treatment of AD in the treatment of neurodegenerative and neuropsychiatric diseases, cardiovascular diseases including congestive heart failure and metabolic diseases including nonalcoholic fatty liver disease ("NAFLD") and nonalcoholic steatohepatitis ("NASH"). Although the Company will focus on the immuno-oncology uses of INB03 in the near term and the treatment of AD with XPro1595, the Company plans to expand the development into these other indications as resources become available. All attempts will be made to fund new research and development with non-dilutive resources that come from grants or revenue from sales of the MSC products.

Since our inception in 2015, we have devoted substantially all of our resources to the discovery and development of our product candidates, including preparing for clinical trials, drug manufacturing and funding general and administrative support for these operations. To date, we have generated no revenue. We have incurred net losses in each year since our inception and, as of December 31, 2018, we had an accumulated deficit of $13,597,868. Our net losses were $12,440,023 and $831,486 for the years ended December 31, 2018 and 2017, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations, including stock-based compensation.

We classify our operating expenses into three categories: royalties and cost of licensing; research and development; and selling, general and administrative expenses. Personnel costs including salaries, benefits, bonuses and stock-based compensation expense comprise a significant component of our research and development and selling, general and administrative expense categories. We allocate expenses associated with our facilities and information technology costs between these two categories based on the nature of each cost.



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As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" under the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- delaying the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies.

We have elected to take advantage of the above-referenced exemptions and we may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenues, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

*Royalties and Cost of Licensing*

Royalties and cost of licensing primarily consists of our expenses related to the generation of revenue from our license agreements. These expenses primarily consist of royalty payments made pursuant to our in-licensing agreements and patent amortization expense. We have in-licensing agreements with various parties for the right to use their products and / or intellectual property. We expect our royalty payments to be small until we advance our products through the clinic and generate sales.

*Research and Development*

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consist of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- manufacturing and testing costs and related supplies and materials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation; and
- facility expenses dedicated to research and development.



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We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

Substantially all of our research and development expenses to date have been incurred in connection with our product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increased number of our product candidates through clinical development, including the conduct of our planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect any of our product candidates to be commercially available for at least the next several years, if ever. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;

- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;



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- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

We may generate a small amount of revenue from MSC product sales in the near future. We do not plan to put a significant commercial infrastructure in place to support the sale of the MSC products. We may partner with specialty groups to help with distribution and sales. We will be opportunistic in sales of the MSC for clinical trials. We do not expect to generate revenue from product sales of INKmune or INB03 until we successfully complete development and obtain marketing approval for one or more of our product candidates. We do not expect that to happen for at least the next several years, if ever. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. Failure to receive additional funding could cause the company to fail.

**Critical Accounting Policies and Significant Judgments and Estimates**

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

***Intangible Assets***

The Company capitalizes costs incurred in connection with in-process research and development purchased from others if the asset has alternative uses and such uses are not restricted under applicable license agreements. Amortization is initiated for acquired in-process research and development intangible assets when their useful lives have been determined. Acquired in-process research and development intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized in research and development expenses. These acquired in-process research and development intangible assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

***Stock-Based Compensation***

We record the fair value of stock options issued to our employees as of the grant date as compensation expense. We recognize compensation expense, net of forfeitures, on a straight-line basis over the requisite service period, which is equal to the applicable vesting period.

We account for equity instruments issued to non-employees using a fair value approach under ASC Subtopic 505-50, *Equity-Based Payments to Non-Employees*. We value equity instruments and stock options granted using the Black-Scholes option-pricing model. The value of non-employee stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.



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On October 3, 2017, the Company entered into an Assignment and Assumption Agreement with Immune Ventures. Pursuant to the Assignment and Assumption Agreement, Immune Ventures assigned all of its rights, obligations and liabilities under the Exclusive License Agreement between the University of Pittsburgh – Of the Commonwealth System of Higher Education and Immune Ventures. Pursuant to the Assignment and Assumption Agreement, the Company agreed to convert the amount Immune Ventures paid of $162,634 into shares of the Company's common stock valued at $7.71 per share, based on the per share value of the shares issued to Xencor, for 21,094 shares for the reimbursement of amounts paid by the Assignor to the University of Pittsburgh, which the Company recorded as stock-based compensation within research and development expense. These shares were issued on December 31, 2017.

During 2017, the Company issued fully vested warrants to purchase 31,667 shares of the Company's common stock to a third party in conjunction with the common stock sold for cash, with an exercise price of $1.50 per share, maturity date of June 30, 2022, and fair value of $36,922 using the Black-Scholes option-pricing model, which were recorded as stock-based compensation.

During March 2018, the CEO and CFO were each granted an option to purchase 400,000 shares of the Company's common stock with a $7.80 exercise price. One-third of the options vested on January 1, 2018 and the remainder shall vest on a monthly basis over a 24 month term. The grant date fair value of these stock options was $5,115,693 based on the Black-Scholes Option Pricing model.

During March 2018, a board member was granted 400,000 shares of the Company's common stock with a $7.80 exercise price. These options vest over a 24-month term. The grant date fair value of these stock options was $2,557,847 based on the Black-Scholes Option Pricing model.

During April 2018, the Company granted options to purchase 108,000 shares of the Company's common stock to each of four Board members, of which 3,000 options shall vest monthly. The options have a 10-year term and a $7.80 exercise price and vest over a 36-month term. The grant date fair value of these stock options was $2,743,894 based on the Black-Scholes Option Pricing model.

On May 16, 2018, the Company entered into a consulting agreement with Pacific Seaboard Investments Ltd. for corporate governance, compliance services regarding the filing of a listing application and assist with activities related to its initial public offering. The term of the consulting agreement is from April 24, 2018 to May 1, 2021. In consideration of the consultant's services, the Company agreed to issue 600,000 shares of its restricted common stock, of which 200,000 shares were to be issued on May 16, 2018 (these shares are not yet issued as of December 31, 2018), 200,000 shares shall be locked up for six months after the effective date of the Company's registration statement and 200,000 shares shall be locked up for 10 months after the date of the Company's offering. The Company recorded stock-based compensation based on the Company's estimate of the fair value of the Company's common stock as of the issuance date, which the Company estimated using the third party valuation it obtained in connection with the acquisition of the Xencor license which valued the Company's common stock at $7.71 per share.

**Off-Balance Sheet Arrangements**

During the periods presented, we did not have any off-balance sheet arrangements as defined under SEC rules.

**Licensing and Collaboration Agreements**

We anticipate that in-licensing, out-licensing and strategic collaborations will become an integral part of our operations, providing the company with opportunities to leverage our partners' expertise and capabilities to further expand the potential of our technologies, product candidates and revenue streams.



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***Xencor***

In October 2017, we licensed INB03, also known as XPro1595, from Xencor. This exclusive, global, unrestricted license came with considerable know-how, intellectual property, pre-clinical data, regulatory documentation and product stocks. Currently, we are focused on the immune-oncology uses of this unique asset. In the future, we may develop the asset in a wide variety of therapeutic areas, with a variety of delivery techniques by ourselves or in conjunction with partners.

**Unit Offering**

In June 2017, the Company completed a private placement in which we sold 1,393,335 of units to accredited investors at a per unit price of $10,000 with each unit consisting of 6,667 shares of our common stock, and received net proceeds of approximately $2,056,000, net of issuance costs of $34,000. Pursuant to the subscription agreement between the Company and the investors of the offering, for a period of two years from June 30, 2017, if the Company sells shares of common stock or the right to receive common stock at a price per share which values the Company at less than $10,000,000, the Company will issue additional shares of common stock to each investor in the offering such that the investor will receive the same effective price per share as the investors in any such future offering, however the Company has not sold its common stock at a valuation of less than $10,000,000 since the inception of this agreement. Pursuant to the subscription agreement, the Company agreed to file a registration statement to register the shares of common stock sold in the offering within five months after the final closing and seek to have the registration statement declared effective by the Securities and Exchange Commission within six months of the filing or else incur penalties, however the Company was unable to meet this timeline. The Company received waivers from all shareholders except for one pursuant to the registration rights. We expect to pay the one investor who did not waive its registration rights approximately $1,500 in penalties. The offer and sale of the units were made in reliance on the exemption from registration afforded under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D under the Securities Act. The unit offering was not conducted in connection with a public offering, and no public solicitation or advertisement was made or relied upon by the investors in connection with the unit offering.

In connection with the offering we paid a registered broker dealer a commission of $47,500, and we issued warrants to purchase 31,667 shares of our common stock with a strike price of $1.50 per share for 5 years from June 30, 2017, with a fair value of $36,922.

**Initial Public Offering**

The Company entered into subscription agreements for the initial public offing ("IPO") and sold, on a best efforts basis, 1,020,820 shares of its common stock, par value $0.001 per share, at a per share purchase price of $8.00 per share (including subscription agreements with insiders of the Company for an aggregate purchase price of $416,000). In connection with the IPO, the Company received gross proceeds of $8,166,560 before deducting placement agent fees and offering expenses. Univest Securities, LLC ("Univest") served as the lead placement agent for the IPO and WallachBeth Capital, LLC and WestPark Capital, Inc. were co-placement agents (Univest, Wallach Beth Capital, LLC and WestPark Capital, Inc. are collectively referred to as the Placement Agents"). In connection with the IPO, the Company paid the Placement Agents $571,659 in commissions and reimbursed Univest for its out-of-pocket expenses.

The Company also agreed to pay Univest an advisory fee of $30,000 upon the closing of the IPO. The fees and expenses paid to the Placement Agents were paid pursuant to the certain Placement Agent Agreement (the "Placement Agent Agreement") between the Company and Univest dated November 16, 2018.

A registration statement relating to the IPO was filed with the Securities and Exchange Commission ("SEC") and was declared effective by the SEC as of December 19, 2018.

The Company also issued the Placement Agents warrants to purchase 40,833 shares of the Company's common stock at an exercise price of $9.60 per share, which warrants are exercisable from time to time, in whole or in part, during the five-year period commencing six months from the effective date Effectiveness Date. If there is no effective registration statement registering the shares of common stock that the warrants may be exercisable into, then the warrants are exercisable on a cashless basis.



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On February 4, 2019, the Company's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INMB".

**Results of Operations**

**Comparison of the Years Ended December 31, 2018 and December 31, 2017**

| | Year Ended | | | |
|---|---|---|---|---|
| | December 31, 2018 | December 31, 2017 | Change | Change |
| | $ | $ | $ | % |
| General and Administrative | $ 11,334,634 | $ 546,118 | $ 10,788,948 | 1,975% |

| | | | | |
|---|---|---|---|---|
| Research and Development | 1,105,389 | 435,362 | 680,027 | 160% |
| Other Income | - | (149,994) | (149,994) | (100)% |
| Net loss | $ (12,440,023) | $ (831,486) | $ 11,618,537 | |

*General and Administrative*

Operating expenses were $11,334,634 for the year ended December 31, 2018, compared to $546,118 for the year ended December 31, 2017. The increase was primarily attributable to stock-compensation, legal, accounting and other consulting fees which included $10,001,359 of stock-based compensation expense incurred in 2018 related to stock options issued to employees and directors and stock payable to a consultant. In addition, the Company incurred $726,242 of professional fees in 2018 related to legal, accounting and other consulting fees.

*Research and Development*

Research and development expenses increased to $1,105,389 for the year ended December 31, 2018 from $435,362 for the year ended December 31, 2017. This increase was due to the start of our Phase I MDSC clinical trial program and the acceptance of the Phase I/II clinical trials.

*Other Income*

Other income earned in 2017 of $149,994 was primarily related to the settlement of a trademark dispute.

**Liquidity and Capital Resources**

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations and otherwise operate on an ongoing basis.

We incurred a net loss of $12,440,023 and $831,486 for the years ended December 31, 2018 and 2017, respectively. Net cash used in operating activities was $2,058,994 and $761,834 for the years ended December 31, 2018 and 2017, respectively. Prior to our February 2019 IPO, we met our liquidity requirements principally through the sale of our common stock in private placements and the sale of our convertible debt to an investor.

As of December 31, 2018, the Company had an accumulated deficit of $13,597,868. Losses have principally occurred as a result of the substantial resources required for research and development of the Company's products which included the general and administrative expenses associated with its organization and product development, as well as the lack of sources of revenues until such time as the Company's products are commercialized. These factors raise substantial doubt about the Company's ability to continue as a going concern from the issuance date of these financial statements. Management plans to pursue additional funding through the issuance of common stock for cash and by implementing its strategic plan to allow the opportunity for the Company to continue as a going concern, however there cannot be any assurance that we will be successful in doing so. With cash on hand plus non-dilutive funding from the R&D credits and the grant from the Alzheimer's Association, the Company estimates it can operate through 2019 and into the first quarter of 2020.



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As of December 31, 2018, we had cash and cash equivalents of $186,204. Also, we raised net proceeds of $7,251,142 (net of placement fees and offering costs of $915,418) from the sale of common stock to the public in an IPO during February 2019. We anticipate our cash and cash equivalents (including the proceeds from our February 2019 IPO will last through December 31, 2019 and into the first quarter of 2020.

At December 31, 2018, we had a cash balance of $186,204, and $1,370,711 as of December 31, 2017. The Company had working capital of $25,576 and $1,589,753, respectively, at December 31, 2018 and 2017. The decrease in our working capital was mainly due to the usage of cash in connection with our clinical trials, and due to the usage of cash in connection with legal, accounting and consulting efforts in anticipation of becoming a public company.

***Cash Flows***

The following table provides information regarding our cash flows for the years ended December 31, 2018 and 2017:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash used in operating activities | $ (2,058,994) | $ (761,834) |
| Net cash used in investing activities | - | (100,000) |
| Net cash provided by financing activities | 900,000 | 2,056,000 |
| Impact on cash from foreign currency translation | (25,513) | 34,886 |
| Net increase (decrease) in cash and cash equivalents | $ (1,184,507) | $ 1,229,052 |

Net Cash Used in Operating Activities

The Company used cash of $2,058,994 and $761,834 in operating activities for the years ended December 31, 2018 and 2017, respectively. The increase in cash used from activities in 2018 compared to 2017 was principally due to the Company incurring additional general and administration expenses and research and development expenses associated with the ongoing operations of the Company during 2018.

Net Cash Used in Investing Activities

The Company used cash of $100,000 in investing activities for the year ended December 31, 2017 in connection with acquisition of in-process research and development intangible assets.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 and 2017 was $900,000 and $2,056,000, respectively, from the proceeds from the sale of common stock.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risk from changes in foreign currency rates.

**Item 8. Financial Statements and Supplementary Data**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**







**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the stockholders and the board of directors of
INmune Bio, Inc.
La Jolla, California

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of INmune Bio, Inc. (the “Company”) as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for the year ended December 31, 2018, 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, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Explanatory Paragraph – Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has suffered recurring losses from operations and has not yet generated any revenue from operations since inception. These conditions 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 2. The consolidated 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 audit. 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 audit 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 of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2017.

Houston, Texas
March 29, 2019





**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the stockholders and the board of directors of
INmune Bio, Inc.
La Jolla, California

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of INmune Bio, Inc. (the "Company") as of December 31, 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year 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, 2017, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

**Other Matters**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not yet generated any revenue from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GBH CPAs, PC

We served as the Company's auditor from 2017 to 2018.

GBH CPAs, PC

Houston, Texas
May 25, 2018



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**INMUNE BIO, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS** | | |
| Cash | $ 186,204 | $ 1,370,711 |
| Research and development tax credit receivable | 592,215 | 106,866 |
| Other tax receivable | 37,382 | 111,618 |
| Joint development cost receivable | 17,989 | 109,124 |
| Prepaid expenses | 15,552 | 42,647 |
| Prepaid expenses – related party | - | 158,504 |
| **TOTAL CURRENT ASSETS** | 849,342 | 1,899,470 |
| Acquired in-process research and development intangible assets | 16,514,000 | 16,514,000 |
| **TOTAL ASSETS** | $ 17,363,342 | $ 18,413,470 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **CURRENT LIABILITIES** | | |
| Accounts payable and accrued liabilities | $ 814,746 | $ 126,257 |
| Accounts payable and accrued liabilities – related parties | 9,020 | 183,460 |
| **TOTAL LIABILITIES** | 823,766 | 309,717 |
| **COMMITMENTS AND CONTINGENCIES** | | |
| **STOCKHOLDERS' EQUITY** | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding | - | - |
| Common stock, $0.001 par value, 200,000,000 shares authorized, 8,719,441 and 8,319,441 shares issued and outstanding, respectively | 8,719 | 8,319 |
| Additional paid-in capital | 25,446,196 | 19,171,237 |
| Common stock issuable | 4,676,000 | 50,000 |
| Accumulated other comprehensive income (loss) | 6,529 | 32,042 |
| Accumulated deficit | (13,597,868) | (1,157,845) |
| **TOTAL STOCKHOLDERS' EQUITY** | 16,539,576 | 18,103,753 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $ 17,363,342 | $ 18,413,470 |

See accompanying notes to these consolidated financial statements.



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**INMUNE BIO, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**FOR THE YEAR ENDED DECEMBER 31, 2018 AND 2017**

| | 2018 | 2017 |
|---|---|---|
| **REVENUE** | $ - | $ - |
| **OPERATING EXPENSES** | | |
| General and administrative | 11,334,634 | 546,118 |
| Research and development | 1,105,389 | 435,362 |
| Total operating expenses | 12,440,023 | 981,480 |
| **LOSS FROM OPERATIONS** | (12,440,023) | (981,480) |
| **OTHER INCOME (EXPENSE)** | | |
| Other expense | - | (6) |
| Gain on legal settlements | - | 150,000 |
| Total other income | - | 149,994 |
| **NET LOSS** | $ (12,440,023) | $ (831,486) |
| Net loss per common share – basic and diluted | $ (1.43) | $ (0.13) |
| Weighted average number of common shares outstanding – basic and diluted | 8,676,701 | 6,564,326 |
| **COMPREHENSIVE LOSS** | | |
| Net loss | $ (12,440,023) | $ (831,486) |
| Other comprehensive income (loss) – gain (loss) on foreign currency translation | (25,513) | 34,886 |
| Total comprehensive loss | $ (12,465,536) | $ (796,600) |

See accompanying notes to these consolidated financial statements.



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**INMUNE BIO, INC.**

**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**
**FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

| | Common Stock | | Additional Paid-In Capital | Common Stock Issuable | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Par Value | | | | | |
| Balance, December 31, 2016 | 5,066,667 | 5,067 | 124,933 | 50,000 | (2,844) | (326,359) | (149,203) |
| Issuance of common stock and warrants in exchange for intangible assets | 1,585,000 | 1,585 | 16,412,415 | - | - | - | 16,414,000 |
| Issuance of common stock for conversion of short term debt – related party | 233,345 | 233 | 349,767 | - | - | - | 350,000 |
| Issuance of common stock for cash | 1,393,335 | 1,393 | 2,054,607 | - | - | - | 2,056,000 |
| Issuance of common stock for settlement of stock payable | 20,000 | 20 | 29,980 | - | - | - | 30,000 |
| Stock-based compensation | 21,094 | 21 | 199,535 | - | - | - | 199,556 |
| Gain on foreign currency translation | - | - | - | - | 34,886 | - | 34,886 |
| Net loss | - | - | - | - | - | (831,486) | (831,486) |
| Balance, December 31, 2017 | 8,319,441 | $ 8,319 | $19,171,237 | $ 50,000 | $ 32,042 | $ (1,157,845) | $ 18,103,753 |
| Issuance of common stock for cash | 400,000 | 400 | 899,600 | - | - | - | 900,000 |
| Common stock issuable for services | - | - | | 4,626,000 | - | - | 4,626,000 |
| Stock-based compensation | - | - | 5,375,359 | - | - | - | 5,375,359 |
| Loss on foreign currency translation | - | - | - | - | (25,513) | - | (25,513) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Net loss | - | - | - | - | - | (12,440,023) | (12,440,023) |
| Balance, December 31, 2018 | 8,719,441 | $ 8,719 | $25,446,196 | $ 4,676,000 | $ 6,529 | $ (13,597,868) | $ 16,539,576 |

See accompanying notes to these consolidated financial statements.



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**INMUNE BIO, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**FOR THE YEAR ENDED DECEMBER 31, 2018 AND 2017**

| | 2018 | 2017 |
|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (12,440,023) | $ (831,486) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 10,001,359 | 199,556 |
| Gain on lawsuit settlements | - | (150,000) |
| Changes in operating assets and liabilities: | | |
| Research and development tax credit receivable | (485,349) | (38,000) |
| Other tax receivable | 74,236 | (76,379) |
| Joint development cost receivable | 91,135 | 47,257 |
| Prepaid expenses | 27,095 | (39,647) |
| Prepaid expenses – related party | 158,504 | (112,042) |
| Accounts payable and accrued liabilities | 688,489 | 68,548 |
| Accounts payable and accrued liabilities – related parties | (174,440) | 170,359 |
| Net cash used in operating activities | (2,058,994) | (761,834) |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Cash paid for acquired in-process research and development intangible assets | - | (100,000) |
| Net cash used in investing activities | - | (100,000) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Net proceeds from sale of common stock | 900,000 | 2,056,000 |
| Net cash provided by financing activities | 900,000 | 2,056,000 |
| Impact on cash from foreign currency translation | (25,513) | 34,886 |
| NET INCREASE (DECREASE) IN CASH | (1,184,507) | 1,229,052 |
| CASH AT BEGINNING OF YEAR | 1,370,711 | 141,659 |
| CASH AT END OF YEAR | $ 186,204 | $ 1,370,711 |
| **SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:** | | |
| Cash paid for income taxes | $ - | $ - |
| Cash paid for interest expense | $ - | $ - |
| **NONCASH INVESTING AND FINANCING ACTIVITIES:** | | |
| Issuance of common stock and warrants for acquired in-process research and development intangible asset | $ - | $ 16,414,000 |
| Conversion of related party debt to common stock | $ - | $ 350,000 |
| Issuance of common stock for settlement of accounts payable | $ - | $ 30,000 |

See accompanying notes to these consolidated financial statements.



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**INMUNE BIO, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 – ORGANIZATION AND BASIS OF PRESENTATION**

***Organization***

INmune Bio, Inc. ("INmune") was originally organized in the State of Nevada on September 25, 2015 and is an early stage specialty pharmaceutical company focused on developing and commercializing our product candidates to treat diseases where the innate immune system is not functioning normally and contributing to the patient's disease. INmune's proprietary is to focus on the innate immune system that include natural killer cells ("NK cells"), myeloid derived suppressor cells ("MDSC cells") and dendritic cells ("DC cells"), which are believed to offer unique therapeutic opportunities. INmune plans to develop their two existing drug platforms: INKmune ("INKmune") which primes NK cells and INB03 ("INB03") which down regulates MDSC cells. Together or individually, the Company expects that these therapies will harness the innate immune system to provide a unique set of therapies for patients with cancer.

INmune Bio International Ltd (England) ("INmune UK") is a wholly owned subsidiary of INmune that was formed on April 6, 2016 in the United Kingdom ("UK"). INmune UK was duly organized under the laws of England and has 1,000 shares owned by INmune. The Company will perform its drug manufacturing and currently performs its drug research and development in the UK and will continue to perform research and development activities in this region. The UK has a research and development ("R&D") rebate program that allows the Company to recover some of its R&D expenses (see further discussion in Note 4).

On March 28, 2018, the Company acquired 100% of INmune Bio Australia Pty Ltd (Australia) ("INmune Australia"). INmune Australia had no assets or liabilities on the acquisition date and was acquired for approximately $2,000. INmune Australia performs drug research and

development and clinical trials in Australia and will continue to perform research and development activities in this region. Australia has an R&D rebate program that allows the Company to recover some of its R&D expenses (see further discussion in Note 4).

***Basis of Presentation and Principles of Consolidation***

The accompanying consolidated financial statements of the Company have been prepared in accordance with Generally Accepted Accounting Principles ("GAAP") in the United States of America and the rules of the Securities and Exchange Commission ("SEC").

The consolidated financial statements herein have been prepared in accordance with GAAP and include the accounts of INmune and its wholly-owned subsidiaries, INmune UK and INmune Australia (collectively the "Company"). All significant intercompany accounts and transactions have been eliminated.



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**NOTE 2 – GOING CONCERN**

As of December 31, 2018, the Company had an accumulated deficit of $13,597,868 and experienced losses since its inception. Losses have principally occurred as a result of the substantial resources required for research and development of the Company's products which included the general and administrative expenses associated with its organization and product development as well as the lack of sources of revenues until such time as the Company's products are commercialized. These factors raise substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of these uncertainties. Management plans to seek additional funding through the issuance of common stock for cash and by implementing its strategic plan to develop its pharmaceutical products and allow the opportunity for the Company to continue as a going concern, however there cannot be any assurance that we will be successful in doing so.

The Company raised net proceeds of approximately $7.2 in February 2019, received $0.6 million in grants in March 2019 and expects to receive an additional $0.4 million in grants on or prior to the first quarter of 2020, which the Company estimates should meet its planned operating requirements into the first quarter of 2020. The Company plans to raise additional capital to meet its future operating requirements until such time as the Company develops a recurring source of revenues, which is not expected for several years. The amount and timing of these capital raises is subject to general market conditions. There are no guarantees that the company will be able to complete these capital raises.

**NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Use of Estimates***

Preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. Actual results and outcomes may differ from management's estimates and assumptions.

***Cash and Cash Equivalents***

For purposes of the statement of cash flows, the Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents.

From time to time, the Company may carry cash balances at financial institutions in excess of the federally insured limit of $250,000.

***Receivables***

Receivables currently consist of an R&D tax credit receivable, valued added tax ("VAT") receivable, joint development cost receivable and a Goods and Services tax ("GST") receivable. The R&D tax credit receivable is recorded when R&D is incurred. At that time, the Company records a receivable for the amount of the credit it expects to receive based on the expenses incurred. The VAT receivable is recorded when the Company receives an invoice with VAT related to it. The receivable is recorded for the amount expected to be returned when the VAT tax return is filed. The joint development cost receivable is recorded when the Company incurs R&D expenses based on the amount it expects to receive as a reimbursement per the Novamune agreement (see Note 4 for detailed explanation of the agreement). The GST tax receivable is recorded when the Company receives an invoice with GST tax related to it. The collectability of these receivables are evaluated periodically based on the actual R&D credit returns submitted, the VAT returns submitted, the GST returns submitted and the amounts received from Novamune. As of December 31, 2018 and December 31, 2017, there were no trade receivables.

***Intangible Assets***

The Company capitalizes costs incurred in connection with in-process research and development purchased from others if the asset has alternative uses and such uses are not restricted under applicable license agreements; patent applications (principally legal fees), patent purchases, and trademarks related to its cell line as intangible assets. Acquired in-process research and development costs that do not have alternative uses are expensed as incurred. Amortization is initiated for acquired in-process research and development intangible assets when their useful lives have been determined. These acquired in-process research and development intangible assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment. During the years ended December 31, 2018 and 2017, the Company recognized impairment related to its intangible assets of $0.



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***Basic and Diluted Loss per Share***

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of outstanding common shares during the period. Diluted loss per share gives effect to all dilutive potential common shares outstanding during the period. Dilutive loss per share excludes all potential common shares if their effect is anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

At December 31, 2018, the Company had 1,632,000 potentially issuable shares of common stock upon the exercise of stock options and 903,611 potentially issuable shares of common stock upon the exercise of warrants.

At December 31, 2017, the Company had 864,668 potentially issuable shares of common stock upon the exercise of warrants.

***Stock-Based Compensation***

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of employee stock option awards at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances.

The Company accounts for equity instruments issued to non-employees using a fair value approach under ASC Subtopic 505-50, *Equity-Based Payments to Non-Employees*. The Company values equity instruments and stock options granted to non-employees at fair value using the Black-Scholes option-pricing model. The value of non-employee stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.

The Company recognizes compensation expense, on a straight-line basis over the requisite service period, which is equal to the applicable vesting period.

***Research and Development***

Research and development ("R&D") costs are expensed as incurred. Research and development credits are recorded by the Company as a reduction of research and development costs. Major components of research and development costs include cash compensation, stock-based compensation, depreciation and amortization expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf.

***Income Taxes***

The Company follows the liability method of accounting for income taxes. Under this method, deferred income tax assets and liabilities are recognized for the estimated tax consequences attributable to differences between the financial statement carrying values and their respective income tax basis (temporary differences). The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.



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***Foreign Currency Translation***

The Company's financial statements are presented in the U.S. dollar ("$"), which is the Company's reporting currency, while its functional currencies are the U.S. Dollar for its U.S. based operations and British Pound ("GBP") for its United Kingdom-based operations and Australian Dollars ("AUD") for its Australian-based operations. All assets and liabilities are translated at the exchange rate on the balance sheet date, stockholders' equity is translated at historical rates and statement of operations items are translated at the weighted average exchange rate for the period. The resulting translation adjustments are reported under other comprehensive income. Gains and losses resulting from the translations of foreign currency transactions and balances are reflected in the statement of operations and comprehensive income (loss).

***New and Recently Issued Accounting Pronouncements***

In January 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02"). This standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company evaluated the effects that the adoption of this new standard will have on its financial statements and does not expect the adoption to have a material impact on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting." ASU 2018-07 aligns accounting for share-based payments issued to nonemployees to that of employees under the existing guidance of Topic 718, with certain exceptions. This update supersedes previous guidance for equity-based payments to nonemployees under Subtopic 505-50, "Equity – Equity-based Payments to Nonemployees." It is effective for annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the impact the adoption of this new standard will have on its financial statements.

***Subsequent Events***

The Company has evaluated all transactions through the financial statement issuance date for subsequent disclosure consideration.

**NOTE 4 – RESEARCH AND DEVELOPMENT ACTIVITY**

According to UK tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in the UK for expenses incurred in R&D subject to certain requirements. INmune UK submits R&D tax credit requests annually for research and development expenses incurred, and recorded a related receivable in the amount of $370,900 and $106,866 as of December 31, 2018 and December 31, 2017, respectively.

According to AUS tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in AUS for expenses incurred in R&D subject to certain requirements. INmune Australia submits R&D tax credit requests annually for research and development expenses incurred. At December 31, 2018 and 2017, the Company recorded a research and development tax credit receivable of $221,761 and $0, respectively for R&D expenses incurred in Australia.

During the years ended December 31, 2018 and 2017, the Company received $0 and $106,096 of R&D tax credit reimbursements, respectively.

The Company is eligible to recover all VAT for all R&D expenses paid. INmune UK recorded an other tax receivable of $6,282 and $111,618 for VAT as of December 31, 2018 and December 31, 2017, respectively.

The Company is eligible to recover all GST for all R&D expenses paid. INmune Australia recorded an other tax receivable of $26,127 and $0 for GST as of December 31, 2018 and December 31, 2017, respectively. During the years ended December 31, 2018 and 2017, no GST was collected.

During the years ended December 31, 2018 and 2017, the Company received $187,728 and $89,329 of VAT reimbursements, respectively.

***Xencor, Inc. License Agreement***

On October 3, 2017, the Company entered into a license agreement ("Xencor License Agreement") with Xencor, Inc. ("Xencor"), which has discovered and developed a proprietary biological molecule that inhibits soluble tumor necrosis factor. Pursuant to the license agreement, Xencor granted the Company an exclusive worldwide, royalty-bearing license in licensed patent rights, licensed know-how and licensed materials (as defined in the license agreement) to make, develop, use, sell and import any pharmaceutical product that comprises, contains, or incorporates Xencor's proprietary protein known as "XPRO1595" that inhibits soluble tumor necrosis factor (or all modifications, formulations and variants of the licensed protein that specifically bind soluble tumor necrosis factor) alone or in combination with one or more active ingredients, in any dosage or formulation ("Licensed Products"). The Company believes the protein has numerous medical applications. Such additional alternative applications of the technology are available under the license agreement. In connection with the license agreement, the Company paid Xencor a one-time non-creditable and non-refundable fee of $100,000 and agreed to issue Xencor shares of the Company's common stock equal to 19% of our fully diluted company shares the value of which are discussed below. The Company also issued warrants to Xencor which is discussed below.



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The Company also agreed to pay Xencor a royalty on Net Sales of all Licensed Products in a given calendar year, which are payable on a country-by- country and licensed product by licensed product basis until the date that is the later of (a) the expiration of the last to expire valid claim covering such Licensed Product in such country or (b) ten years following the first sale to a third party of the licensed product in such country.

Under the Xencor License Agreement, the Company also agreed to pay Xencor a percentage of any sublicensing revenue that it receives.

In connection with the Xencor License Agreement, the Company entered into a stock issuance agreement with Xencor pursuant to which it issued Xencor 1,585,000 shares of its common stock with a fair value of $12,221,000 based on the discounted cash flow method of the income approach as set forth in an independent valuation report dated November 17, 2017, and fully vested warrants to purchase an additional number of shares of common stock equal to 10% of the fully diluted company shares immediately following such purchase with a fair value of $4,193,000 based on the Black-Scholes Option Pricing Model.

The warrants have an exercise price based on a valuation of the Company at $100,000,000 and expire on October 3, 2023. The aggregate purchase price for the full exercise of the option is $10,000,000 which purchase price shall be pro-rated for any partial exercise of the Option. In August 2018, we entered into a First Amendment to Stock Issuance Agreement. Pursuant to the amendment, the purchase price for the additional shares may only be paid by cash. In connection with the stock issuance agreement, the Company, Xencor and more than 90% of shareholders as of September 30, 2017 ("Key Holders") entered into a voting agreement. Pursuant to the voting agreement, Xencor and the Key Holders agreed to vote their respective shares to vote one individual designated by the holder of a majority of Xencor's shares of the Company's common stock to the Company's board of directors. The voting agreement shall continue in full force and effect from the date hereof through the earliest of the following dates, on which date it shall terminate in its entirety: (a) the date of a qualified offering, as defined in the issuance agreement; (b) ten (10) years from the date of this Agreement; (c) the date of the closing of a qualified sale, as defined in the issuance agreement; or (d) the date as of which the parties hereto terminate this agreement by written consent of the holders of a majority of the Investor Shares. The voting agreement terminated upon completion of our IPO during February 2019.

The Company recorded $16,514,000 for the acquisition of intangible assets for the in-process research and development in 2017 as the fair value of the cash, stock and warrants on the date of the License Agreement acquisition in accordance with Accounting Standards Codification 730 – *Research and Development.* The Company has the license rights to pursue alternative applications of the technology as part of its future development plans.

***Novamune Joint Development Agreement***

On September 3, 2016, the Company entered into a joint development agreement with Novamune, Inc. ("Novamune") (the "Development Agreement"). Novamune is owned by a significant shareholder of the Company. Novamune had previously developed and licensed technology relating to ex-vivo activation of NK cells for the treatment of cancer and other diseases. The parties agreed to exclusively collaborate on the further development of technologies related to NK cells for therapeutic applications. The Company and Novamune agreed to share equally in the costs related to such joint development projects and agreed to jointly own any intellectual property developed by the joint projects, provided that Novamune shall have an exclusive royalty free license to use any such intellectual property relating to ex-vivo applications and the Company shall have an exclusive royalty free license to use any such intellectual property relating to in-vivo applications. The Development Agreement is subject to Novamune or affiliates investing a total of $1,250,000 in the Company, of which $350,000 was advanced through a convertible note payable in 2016 (see further discussion in Note 5) and $900,000 was received from Luminus, a Novamune affiliate, during the year ended December 31, 2018 in exchange for the issuance of 400,000 shares of the Company's common stock. As of December 31, 2018 and 2017, the Company had a joint development receivable outstanding related to Novamune's portion of R&D costs incurred of $17,989 and $109,124, respectively.



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***INKmune License Agreement***

On October 29, 2015, the Company entered into an exclusive license agreement with Immune Ventures, LLC ("Immune Ventures"), owner of all of the rights related to our principal patent (the "INKmune License Agreement"). Pursuant to the INKmune License Agreement, the Company was granted exclusive worldwide rights to the patents, including rights to incorporate any improvements or additions to the patents that may be developed in the future. In consideration for the patent rights, the Company agreed to the following milestone payments (of which none have been met as of December 31, 2018):

| | |
|---|---|
| Each Phase I initiation | $ 25,000 |
| Each Phase II initiation | $ 250,000 |
| Each Phase III initiation | $ 350,000 |
| Each NDA/EMA filing | $ 1,000,000 |
| Each NDA/EMA awarded | $ 9,000,000 |

In addition, the Company agreed to pay the licensor a royalty of 1% of net sales during the life of each patent granted to the Company. The License is owned by RJ Tesi, the Company's President and a member of our Board of Directors, David Moss, its Chief Financial Officer and Treasurer and Mark Lowdell, its Chief Scientific Officer. As of December 31, 2018 and December 31, 2017, no sales had occurred under this license.

The term of the agreement began on October 29, 2015 and, if not terminated sooner pursuant to the agreement, ends on a country by country basis on the date of the expiration of the last to expire patent rights where patent rights exists. Upon the termination of the agreement we shall have a fully paid up, perpetual, royalty-free license without further obligation to Immune Ventures. The agreement can be terminated by Immune

Ventures if, after 60 days from our receipt of notice that we have not made a payment under the agreement, and we still do not make this payment. On July 20, 2018, the parties amended the agreement under which the Company is required achieve the following milestones:

Filing of IND or equivalent, by October 29, 2019
Initiation of Phase 1 clinical or equivalent trials by October 29, 2020
Initiation of Phase II clinical trials or equivalent by October 29, 2022
Initiation of Phase III clinical trials or equivalent by October 29, 2024
Filing of NDA or equivalent by October 29, 2025 or equivalent

If the Company doesn't achieve the above milestones, it is required to negotiate in good faith with Immune Ventures to determine how it can either remedy the failure or achieve an alternate development. If the Company fails to make any required efforts or if the efforts do not remedy the situation within 60 days of written notice by Immune Ventures then Immune Ventures may provide notice to terminate the license or convert it to a non-exclusive license.

***University of Pittsburg License Agreement***

On October 3, 2017, the Company entered into an Assignment and Assumption Agreement with Immune Ventures related to intellectual property licensed from the University of Pittsburgh. Pursuant to the Assignment and Assumption Agreement ("Assignment Agreement"), Immune Ventures assigned all of its rights, obligations and liabilities under an Exclusive License Agreement between the University of Pittsburgh – Of the Commonwealth System of Higher Education ("Licensor") and Immune Ventures to INmune Bio ("Licensee"), (the "PITT Agreement"). Pursuant to the Assignment Agreement, the Company agreed to convert the amount Immune Ventures paid of $162,634 into shares of the Company's common stock at $7.71 per share, based on the per share value of the shares issued to Xencor, for 21,094 shares for the reimbursement of amounts paid by the Assignor to the University of Pittsburgh, which the Company recorded as stock-based compensation within research and development expense. These shares were issued on December 31, 2017.

Consideration under the PITT Agreement includes: (i) annual maintenance fees, (ii) royalty payments based on the sale of products making use of the licensed technology, and (iii) milestone payments.



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Annual maintenance fees under the PITT Agreement include: $5,000 due June 26 of each year 2018-2022; $10,000 due on June 26 of each year 2023-2024; and $25,000 due on June 26 of each year 2025 and annually thereafter until first commercial sale.

| | | |
|---|---|---|
| June 26 of each year 2018-2022 | $ | 5,000 |
| June 26 of each year 2023-2024 | $ | 10,000 |
| June 26 of each year 2025 until first commercial sale | $ | 25,000 |

Upon first commercial sale of a product making use of the licensed technology under the PITT Agreement, the Licensee is required to pay royalties equal to 2.5% of Net Sales each calendar quarter.

Moreover, under the PITT Agreement the Licensee is required to make milestone payments as follows:

| | | |
|---|---|---|
| Each Phase I initiation | $ | 50,000 |
| Each Phase III initiation | $ | 500,000 |
| First commercial sale of product making use of licensed technology | $ | 1,250,000 |

A Phase I study was initiated in 2018, and the Company recorded $50,000 of research and development expense during the year ended December 31, 2018 pursuant to this milestone payment schedule. The PITT Agreement expires upon the earlier of: (i) expiration of the last claim of the Patent Rights forming the subject matter of the PITT Agreement; or (ii) the date that is 20 years from the effective date of the agreement (June 26, 2037).

Licensee may terminate the PITT Agreement upon 3 months prior written notice provided all payments under the license are current. Licensor may terminate the PITT Agreement upon written notice if: (i) Licensee defaults as to performance of material obligations which have not been cured within 60 days after receiving written notice; or (ii) Licensee ceases to carry out its business, becomes bankrupt or insolvent, applies for or consents to the appointment of a trustee, receiver or liquidator of its assets or seeks relief under any law for the aid of debtors.

**NOTE 5 – RELATED PARTY TRANSACTIONS**

A significant shareholder of the Company is also the owner of various companies that conduct business with the Company, including Luminus Holdings, Inc. ("Luminus"), Novamune, and Advent Bioservices, Inc. ("Advent Bioservices").

***Short-term debt – related party***

On May 9, 2016, the Company received cash proceeds of $350,000 from the issuance of a convertible note to Novamune that matured on August 1, 2016, with a conversion rate of $1.50 per share, and an annual interest rate of 8%. On September 3, 2016, the maturity date was extended to March 3, 2017. During the year ended December 31, 2017, the convertible note was converted into 233,345 shares of common stock of the Company. Novamune is owned by a significant shareholder of the Company.

***Prepaid expense – related party***

At December 31, 2018 and 2017, the Company had prepaid expense of $0 and $158,504, respectively, paid to UCL Consultants Limited, a wholly owned subsidiary of the University of London, in connection with medical research performed on behalf of the Company. The Company's Chief Scientific and Manufacturing Officer is a professor at the University of London.



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***Accounts payable and accrued liabilities – related parties***

At December 31, 2018 and 2017, the Company owed Advent Bioservices $0 and $173,314, respectively, for medical research provided on behalf of the Company. Advent Bioservices is owned by a significant shareholder of the Company. At December 31, 2018 and 2017, the Company owed UCL Consultants Limited $9,020 and $0, respectively, in connection with medical research performed on behalf of the Company.

**NOTE 6 – COMMITMENTS AND CONTINGENCIES**

***Litigation settlement***

In November 2016, an individual filed an action in Cook County, Illinois, against the Company; David J. Moss, its Chief Financial Officer, Treasurer and Secretary ; and Raymond J. Tesi, its president and Chief Executive Officer (the Company, Mr. Moss and Mr. Tesi are referred to collectively as the "Company Parties"). The action alleged claims against the Company Parties concerning payment of monies and/or securities allegedly owed. In April 2017, the Company Parties and the Claimant entered into a Settlement Agreement and Mutual General Release agreement with that individual (the "Settlement Agreement"). Pursuant to the Settlement Agreement, the Company agreed to issue 33,335 shares of the Company's common stock valued at $50,000, based on the value of the stock of the last round of financing of $1.50 per share. The Company assessed the value of the common stock owed as of December 31, 2017, and determined that the $1.50 per share value form the most recent round of financing was still the most readily determinable value of the shares of the Company's common stock issuable as a part of this settlement. These shares have not been issued and are subject to a restriction on transfer for a period of two years from the date the Company completes an initial public offering or otherwise becomes a public company after which the Company will deliver the shares to the Claimant. The agreement to issue the shares following the two-year restriction period was a full and complete settlement of all claims that the Claimant may have had against the Company Parties and the Cook County action was dismissed with prejudice. The obligation was recorded as common stock issuable of $50,000 as of December 31, 2018 and 2017, respectively, pending delivery of the shares to the Claimant after the restriction period expires.

***Trademark settlement***

During 2017, the Company received notice that another company had filed a trademark application with the United States Patent and Trademark Office to register a certain trademark. The Company filed an opposition in the United States Trademark Trial and Appeal Board. Subsequently, INmune and the other company entered into a settlement agreement pursuant to which the Company agreed not to oppose the other company's trademark and the other company paid INmune cash proceeds of $150,000 in full consideration for the settlement agreement, which the Company recorded as other income in the consolidated statement of operations for the year ended December 31, 2017.

**NOTE 7 – STOCKHOLDERS' EQUITY**

The Company is authorized to issue up to 200,000,000 shares of common stock at par value $0.001 per share and 10,000,000 shares of preferred stock at a par value of $0.001 per share.

During the year ended December 31, 2018, to complete a series of funding provided for in the Company's joint development agreement dated September 3, 2016, the Company received $900,000 in cash from Luminus in exchange for 400,000 shares of the Company's common stock. Luminus is owned by a significant shareholder of the Company.

On May 16, 2018, the Company entered into a consulting agreement with Pacific Seaboard Investments Ltd. for corporate governance, compliance services regarding the filing of a listing application and assist with activities related to its initial public offering. The term of the consulting agreement is from April 24, 2018 to May 1, 2021. In consideration of the consultant's services, the Company agreed to issue 600,000 shares of its restricted common stock, of which 200,000 shares were to be issued on May 16, 2018, 200,000 shares shall be locked up for six months after the effective date of the Company's registration statement and 200,000 shares shall be locked up for 10 months after the date of the Company's offering. Pursuant to this agreement, the Company recorded $4,626,000 of stock-based compensation expense during the year ended December 31, 2018 for the 600,000 shares of common stock to be issued.



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During the year ended December 31, 2017, the Company issued 1,393,335 shares of the Company's common stock for cash proceeds of $2,056,000 valued at approximately $1.50 per share.

During the year ended December 31, 2017, the Company issued 233,345 shares of its common stock for the conversion of the full value of the Company's outstanding convertible debt (converted at no interest) of $350,000 valued at approximately $1.50 per share.

As of December 31, 2018 and 2017, the Company recorded common stock issuable of $50,000 for 33,335 common shares related to a legal settlement valued at approximately $1.50 per share (see Note 6).

During 2017, in connection with the Xencor License Agreement, the Company entered into a stock issuance agreement with Xencor pursuant to which it issued Xencor 1,585,000 shares of its common stock valued in total at $12,221,000 (see Note 4).

On October 3, 2017, the Company entered into an Assignment and Assumption Agreement with Immune Ventures. Pursuant to the Assignment and Assumption Agreement, Immune Ventures assigned all of its rights, obligations and liabilities under the Exclusive License Agreement between the University of Pittsburgh – Of the Commonwealth System of Higher Education and Immune Ventures. Pursuant to the Assignment and Assumption Agreement, the Company agreed to convert the amount Immune Ventures paid of $162,634 into shares of the Company's common stock at $7.71 per share, based on the per share value of the shares issued to Xencor, for 21,094 shares for the reimbursement of amounts paid by the Assignor to the University of Pittsburgh, which the Company recorded as stock-based compensation within research and development expense. These shares were issued on December 31, 2017.

***Stock options***

During the year ended December 31, 2018, the CEO and CFO were each granted an option to purchase 400,000 shares of the Company's common stock with a $7.80 exercise price. One-third of the options vested on January 1, 2018 and the remainder shall vest on a monthly basis over a 24-month term. The grant date fair value of these stock options was $5,115,693 based on the Black-Scholes Option Pricing model.

During the year ended December 31, 2018, a board member was granted 400,000 shares of the Company's common stock with a $7.80 exercise price. These options vest over a 24-month term. The grant date fair value of these stock options was $2,557,847 based on the Black-Scholes Option Pricing model.

During April 2018, the Company granted options to purchase 108,000 shares of the Company's common stock to each of four Board members, of which 3,000 options shall vest monthly per grant. The options have a 10-year term and a $7.80 per share exercise price and vest over a 36-month term. The grant date fair value of these stock options was $2,743,894 based on the Black-Scholes Option Pricing model.



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A summary of stock option activity is presented in the table below:

| | | Weighted- | Weighted-average |
|---|---|---|---|

| | Number of Shares | average Exercise Price | Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2017 | - | $ - | - | $ - |
| Granted | 1,632,000 | 7.80 | 10.0 | - |
| Exercised | - | - | - | - |
| Expired/Forfeited | - | - | - | - |
| Outstanding at December 31, 2018 | 1,632,000 | $ 7.80 | 9.07 | $ - |
| Exercisable at December 31, 2018 | 841,333 | $ 7.80 | 9.03 | $ - |

During the year ended December 31, 2018, the 1,632,000 options that were granted had a weighted average grant-date fair value of $6.37 per share. During the year ended December 31, 2018, the Company recognized stock-based compensation expense of $5,375,359 related to stock options. As of December 31, 2018, there was approximately $5,042,075 of total unrecognized compensation cost related to non-vested stock options which is expected to be recognized over a weighted-average period of approximately 1.51 years.

The fair values of the options granted during the year ended December 31, 2018 were estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

| | |
|---|---|
| Market value of common stock on grant date | $ 7.71 |
| Risk free interest rate (1) | 2.40% - 2.56% |
| Dividend yield | None |
| Volatility factor (2) | 262%-267% |
| Weighted average expected life in years (3) | 5.75 |
| Expected forfeiture rate | 0% |

(1) The risk-free interest rate was determined by management using the U.S. Treasury zero-coupon yield over the contractual term of the option on date of grant.

(2) Due to a lack of stock volatility history, the Company uses peer companies to estimate the volatility factor.

(3) Due to a lack of stock option exercise history, the Company uses the simplified method under SAB 107 to estimate expected term.

***Warrants***

On June 30, 2017, the Company issued fully vested warrants to purchase 31,667 shares of the Company's common stock to a third party in conjunction with the common stock sold for cash, with an exercise price of $1.50, maturity date of June 30, 2022, and fair value of $36,922 using the Black-Scholes option-pricing model, which were recorded as stock-based compensation. The assumptions used for these warrants consisted of an exercise price of $1.50, expected dividends of 0%, expected volatility of 106.55%, a risk free rate of 1.89% an expected life of 5 years.

In connection with the Xencor License Agreement, the Company issued fully vested warrants to purchase an additional number of shares of common stock equal to 10% of the fully diluted Company shares immediately following such purchase. The fair value of these warrants was valued at $4,193,000 based on the Black-Scholes Option Pricing Model. The assumptions used for these warrants consist of an exercise price of $10,000,000, expected dividends of 0%, expected volatility of 84.9%, a risk free rate of 2.04% an expected life of 6 years.



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**NOTE 8 – INCOME TAXES**

The provision for income taxes consists of the following components:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Current expense (benefit) | $ - | $ - |
| Federal | - | - |
| Foreign | - | - |
| Current income tax expense | - | - |
| | | |
| Deferred expense (benefit) | - | - |
| Federal | - | - |
| Foreign | - | - |
| Deferred income tax | - | - |
| Net deferred taxes | $ - | $ - |

A reconciliation of income tax benefit computed using the federal statutory income tax rate to the Company's tax expense is as follows:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Federal tax benefit at statutory rate | $ (2,612,404) | $ (282,704) |
| Stock-based compensation | 1,546,922 | 7,754 |
| State income tax benefit, net of federal tax effect | (418,095) | (24,104) |
| Foreign tax differential | (4,019) | 8,988 |
| Reduction of deferred taxes due to US tax reform | - | 70,704 |
| Change in valuation allowance | 1,487,596 | 219,362 |
| Income tax benefit | $ - | $ - |

The principal components of deferred tax assets and liabilities consist of the following at December 31, 2018 and 2017, respectively:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Deferred tax assets | | |
| Stock-based compensation | $ 971,460 | $ - |
| Federal NOL carryforwards | 355,568 | 69,798 |
| Foreign NOL carryforwards | 340,005 | 109,639 |

| | | |
|---|---|---|
| Total deferred tax assets | 1,667,033 | 179,437 |
| Less valuation allowance | (1,667,033) | (179,437) |
| Net deferred tax assets | $ - | $ - |



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New Tax reform legislation was enacted on December 22, 2017, known as the Tax Cuts and Jobs Act of 2017 ("The Act"). The Act moved from a worldwide tax system to a quasi-territorial tax system and was comprised of broad and complex changes to the U.S. tax code including, but not limited to, (1) reduced the U.S. tax rate from 35% to 21%; (2) added a deemed repatriation transition tax on certain foreign earnings and profits; (3) generally eliminated U.S. federal income taxes on dividends from foreign subsidiaries; (4) included certain income of controlled foreign companies in U.S. taxable income ("GILTI"); (5) created a new minimum tax referred to as a base erosion anti-abuse income tax; (6) limited certain U.S. Federal research based credits; and (7) eliminated the domestic manufacturing deduction. The accounting for the reduction of deferred tax asset and the tax charge for the deemed repatriation transition tax is complete as of December 31, 2018. The rate change, along with certain immaterial changes in tax basis resulting from The Act, resulted in a reduction of the Company's deferred tax assets of approximately $71,000 and a corresponding reduction in the valuation allowance.

At December 31, 2018, the Company had a federal net operating loss carryforward of approximately $1.7 million. The net operating loss carryforwards for 2017 will begin to expire in the year ending December 31, 2037. The net operating loss carryforwards starting in 2018 have no expiration. The change in the valuation allowance was $1,487,596 during the year ended December 31, 2018.

The Company recognizes uncertain tax positions in accordance with ASC 740 on the basis of evaluating whether it is more likely than not that the tax positions will be sustained upon examination by tax authorities. For those tax positions that meet the more-likely-than not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement. As of December 31, 2018, and 2017, the Company has no significant uncertain tax positions. There are no unrecognized tax benefits included on the balance sheet that would, if recognized, impact the effective tax rate. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

**NOTE 9 – SUBSEQUENT EVENTS**

During February 2019, the Company completed its initial public offering in which the Company sold 1,020,820 shares of its common stock for gross proceeds of $8,166,560 (net proceeds of $7,251,142).

The Company also issued the placement Agents warrants to purchase 40,833 shares of the Company's common stock at an exercise price of $9.60 per common share, which warrants are exercisable until December 18, 2023.

During February 2019, the Company was awarded a grant to receive $1,000,000 from the Alzheimer's Association to advance XPro1595, a novel therapy targeting neuroinflammation as a cause of Alzheimer's disease. The $1,000,000 award will be paid to the Company in tranches based on the company's Company's achieving certain specified milestones over the course of the Phase 1 clinical trial. During March 2019, the Company received $600,000 in cash pursuant to this grant.



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

None.

**Item 9A. Controls and Procedures**

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, due to the small size of the Company and limited segregation of duties, our disclosure controls and procedures were not effective as of December 31, 2018.

*Management's Annual Report on Internal Control over Financial Reporting*

This Annual Report does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

*Changes in Control over Financial Reporting*

There have been no changes in our internal control over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**



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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

## MANAGEMENT

The following table sets forth our executive officers and directors, their ages and position(s) with the Company.

| Name | Age | Position |
|---|---|---|
| Raymond J. Tesi, MD | 63 | President and CEO, and Director |
| David J. Moss | 49 | Chief Financial Officer, Treasurer and Secretary |
| Mark Lowdell, PhD | 56 | Chief Scientific Officer |
| J. Kelly Ganjei | 45 | Director |
| Tim Schroeder | 60 | Director |
| David Szymkowski, PhD | 55 | Director |
| Scott Juda, JD | 48 | Director |

Directors are elected annually and hold office until the next annual meeting of the stockholders of the Company and until their successors are elected. Officers are elected annually and serve at the discretion of the Board of Directors.

***Raymond J. Tesi, M.D.*** has been our President, Chief Executive Officer and a member of the board of directors of the Company since the formation of the Company in September 2015. From November 2011 until May 2015, Dr. Tesi was CEO, President and Acting Chief Medical Officer of FPRT Bio Inc., a development stage biotech formed to develop XPro1595 for the treatment of neurodegenerative disease and other inflammatory diseases. From November 2010 to October 2011, Dr. Tesi was Chief Medical Officer of Adienne SRL, an emerging biotech in Bergamo, Italy focused on products to treat patients with hematologic malignancy. From June 2007 to September 2010, Dr. Tesi was founder, CEO and President of Coronado Biosciences. Dr. Tesi received his MD degree from Washington University School of Medicine in 1982. Dr. Tesi has been a licensed physician since 1982 and Fellow of the American College of Surgery since 1991. Dr. Tesi's significant experience with our licensed technology and his experience as a transplant surgeon, entrepreneur, investor and director of start-up biopharmaceutical companies were instrumental in his selection as a member of the board of directors.

***David J. Moss, M.B.A.*** has been the Chief Financial Officer since our formation in September 2015. From September 15, 2015 until April 2018, Mr. Moss was also a member of our board of directors. Mr. Moss is a director of CareSpan International, Inc. and served as a director of Pegasi Energy Resources Corporation from May 2007 to January 2014 and was a founding investor in Reliant Service Group LLC which recently sold in 2015 to a leading private equity firm. From 1996 until 2001 he served as Managing Partner at a Seattle based venture capital firm, The Phoenix Partners. From November 2010 until October 2011, Mr. Moss was the Chief Executive Officer, sole director and a majority shareholder of Tamandare Explorations Inc. a private specialty pharmaceutical company. In October 2011 Tamandare Explorations engaged in a merger transaction pursuant to with Tonix Pharmaceuticals Holding Corp., which at the time had its common stock listed on the OTC Bulletin Board and is currently listed on Nasdaq Capital Market. In connection with the merger transaction Mr. Moss resigned as Tamandare Explorations Chief Executive Officer and a member of its board of directors. From 2001 until the formation of INmune Bio in 2015, Mr. Moss has invested in healthcare technology companies. Mr. Moss holds an MBA from Rice University and a BA in Economics from the University of California, San Diego.



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***Mark Lowdell, Ph.D.*** was a member of the board of directors of the Company from its formation in September 2015 until July 2018 and has been our Chief Scientific Officer since October 2015. Prof. Lowdell is Professor of Cell and Tissue Therapy at University College London where he has led a translational immunotherapy group since 1994. Since February 2009, Prof. Lowdell has also been Director of Cellular Therapy at the Royal Free London NHS Foundation Trust. He received his PhD in clinical immunology from London Hospital Medical College, University of London in 1992 and is a qualified immunopathologist. Prof. Lowdell's education and significant academic and clinical experience with cellular therapies were instrumental in his selection as Chief Scientific Officer.

***Timothy Schroeder*** has been one of our directors since December 2016. Timothy Schroeder, CEO and Founder of CTI Clinical Trial & Consulting Services ("CTI"), has over 35 years of clinical, academic, and industry experience in global drug and device development programs. CTI, founded in 1999, is a multi-national research firm with associates in North America, Europe, Latin America and Asia-Pacific. The firm has supported more than 100 drug and device approvals, and currently works on behalf of approximately 120 global pharmaceutical and biotechnology companies. Prior to founding CTI, Mr. Schroeder held numerous faculty positions with the University of Cincinnati College of Medicine. He was also the founding Executive Vice President of Clinical Development at SangStat Medical Corporation, which went public in 1995. Mr. Schroeder is currently a board member for over a dozen corporate and non-profit organizations, including Xavier University, which he attended. Mr. Schroeder was named as an EY Entrepreneur of the Year in 2015 and was recognized as Top Leader by the Enquirer Media in 2016. Mr. Schroder has significant clinical trial and drug development experience which is why he was selected as a member of the board of directors

***David Szymkowski, Ph.D*** has been one of our directors since August 2018. Dr. Szymkowski has been the vice president of Cellular biology at Xencor, Inc. since 2016. Xencor whose common stock is listed on NASDAQ is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for treatment of autoimmune diseases, asthma and allergic diseases and cancer. David E. Szymkowski leads the immunology group as Vice President of Cell Biology at Xencor Inc. where he is focused on translational development of Fc-engineered and bispecific antibodies for the treatment of autoimmune diseases, allergic diseases, and cancer. Prior to joining Xencor in 2002, Dr. Szymkowski was a principal scientist in the respiratory group at Roche Bioscience in Palo Alto, CA. Previously, he was a virology program leader at Roche Pharmaceuticals in the U.K. With 25 years of big pharma and biotech R&D experience at Roche and at Xencor, Dr. Szymkowski has been instrumental in 10 IND submissions, coauthored over forty papers and reviews, is an inventor on over a dozen patents, and speaks frequently on the development of antibody therapeutics and other biologics. Dr. Szymkowski has contributed to the advancement of numerous antibody drugs into clinical trials for lupus, asthma, allergy, and hematological and solid tumors. He received his B.A. at Johns Hopkins University and his Ph.D. in molecular and cell biology from Penn State, and completed a postdoc at the Imperial Cancer Research Fund (U.K.). Dr. Szymkowski serves on the board as the Xencor representative pursuant to a voting agreement with other shareholders of the Company, and has significant experience in pharmaceutical business development.

***J. Kelly Ganjei,*** has been one of our directors since September 2016. Mr. Ganjei joined Cognate BioServices, Inc. in 2011 as the Chief Executive Officer. Mr. Ganjei has over 20 years of experience within the life science, venture capital and IT sectors and has lead companies through various stages of development, ranging from the virtual start-up, to the mid-cap restart, through the exponential growth phase, and into a public exit. Prior to joining Cognate, Mr. Ganjei was the principal at an SBA venture capital firm where he was brought on to support deal flow into and out of the fund, with a specific focus on regenerative medicine, immunotherapy and cell therapy investment opportunities. While in this role, he helped the venture capital firm exit the SBA program and was the key driver of several other strategic deals for various portfolio companies. Previously, Mr. Ganjei was the CEO and Co-founder of Remegenix, Inc. Prior to Remegenix, Inc., was a Vice President of Business

Development at TissueGene, Inc., Mr. Ganjei helped close several tranches of TissueGene's Series A and B funding and was responsible for developing the global informatics infrastructure for the company and its affiliates. Prior to TissueGene, Inc., Mr. Ganjei served as a Product Marketing Manager for LabVantage where he was the key technical sales and marketing lead for LabVantage's life science software product offering globally and was responsible for the design of all life science product initiatives. Mr. Ganjei has published numerous scientific, peer-reviewed papers in a number of journals and has been an invited guest speaker and presenter at various business forums. Mr. Ganjei received his B.S. in Microbiology from the University of Maryland College Park in 1995 and began his career at NIH in May of the same year. Mr. Ganjei has significant biotechnology start-up experience along with drug manufacturing knowledge which is why he was selected as a member of the board.



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***Scott Juda,*** has been one of our directors since March 2018. He is the Manager and Co-Founder of Fossick Capital, a technology focused hedge fund. From 2012 to 2016, Scott was the Chief Executive Officer and Co-Founder of The Juda Group, Inc., a division of CCM, an institutional capital markets focused broker-dealer. Scott was at SMH Capital from 2002 until 2011, serving as a Managing Director in the Investment Banking Group as well Chief Operating Officer of The Juda Group subsidiary. From 2000 to 2002, Mr. Juda was an institutional sales-trader for Sutro & Co. From 1997 to 2000, Scott practiced corporate and securities law at Buchalter Nemer LLP. Mr. Juda received his bachelor's degree from the University of Southern California and his juris doctor from the University of Pepperdine School of Law. Mr. Juda is a member of the State Bar of California.

**Family Relationships**

None.

**Corporate Governance**

We are committed to maintaining strong corporate governance practices that benefit the long-term interests of our Shareholders by providing for effective oversight and management of the Company. Our governance policies, including our Corporate Communications Policy, Insider Trading Policy, Code of Conduct, and Committee Charters can be found on our website at http://www.inmunebio.com/.

The Nominating and Corporate Governance Committee regularly reviews our corporate governance policies, Code of Conduct, and Committee Charters to ensure that they take into account developments at the Company, changes in regulations and listing requirements, and the continuing evolution of best practices in the area of corporate governance.

The Board conducts an annual self-evaluation in order to assess whether the directors, the committees, and the Board are functioning effectively.

The Board has granted Mark Lowdell and David Moss rights to observe board meetings as long as they each own at least 750,000 shares of the Company's common stock.

**Code of Ethics**

We have recently adopted a Code of Ethics that applies to our principal executive officers and principal financial officer, principal accounting officer or controller, or persons performing similar functions and also to other employees. Our Code of Ethics can be found on our website at www.inmunebio.com.

**Involvement in Certain Legal Proceedings**

Except as disclosed in the bios above, our Directors and Executive Officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;

4. being found by a court of competent jurisdiction in a civil action, the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

5. being subject of, or a party to, any federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

6. being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.



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**Board Committees**

Our Board of Directors has established three standing committees: an audit committee, a nominating and corporate governance committee and a compensation committee, which are described below. Members of these committees are elected annually at the regular board meeting held in conjunction with the annual stockholders' meeting. The charter of each committee is available on our website at www.inmunebio.com.

**Audit Committee**

The Audit Committee, among other things, is responsible for:

- Appointing, approving the compensation of, overseeing the work of, and assessing the independence, qualifications, and performance of the independent auditor;
- reviewing the internal audit function, including its independence, plans, and budget;
- approving, in advance, audit and any permissible non-audit services performed by our independent auditor;
- reviewing our internal controls with the independent auditor, the internal auditor, and management;
- reviewing the adequacy of our accounting and financial controls as reported by the independent auditor, the internal auditor, and management;
- overseeing our financial compliance system; and
- overseeing our major risk exposures regarding the Company's accounting and financial reporting policies, the activities of our internal audit function, and information technology.

The Board has affirmatively determined that each member of the Audit Committee meets the additional independence criteria applicable to audit committee members under SEC rules and the NASDAQ Stock Market. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee. The Board has affirmatively determined that each member of the Audit Committee is financially literate, and that all members meet the qualifications of an Audit Committee financial expert. The Audit Committee consists of Tim Schroeder, Scott Juda and Kelly Ganjei. Scott Juda is the chairman of the Audit Committee.

**Compensation Committee**

The Compensation Committee is responsible for establishing and administering our executive compensation policies. The role of the Compensation Committee is to (i) formulate, evaluate and approve compensation of the Company's directors, executive officers and key employees, (ii) oversee all compensation programs involving the use of the Company's stock, and (iii) produce, if required under the securities laws, a report on executive compensation for inclusion in the Company's proxy statement for its annual meeting of shareholders. The duties and responsibilities of the Compensation Committee under its charter include:



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- Annually reviewing and setting compensation of executive officers;
- Periodically reviewing and making recommendations to the Board with respect to compensation of non-employee directors;
- Reviewing and approving corporate goals and objectives relevant to Chief Executive Officer compensation, evaluating the Chief Executive Officer's performance in light of those goals and objectives, and setting the Chief Executive Officer's compensation levels based on this evaluation;
- Reviewing competitive practices and trends to determine the adequacy of the executive compensation program;
- Approving and overseeing incentive compensation and equity-based plans for executive officers that are subject to Board approval;
- Making recommendations to the Board as to the Company's compensation philosophy and overseeing the development and implementation of compensation programs;
- Periodically reviewing and making recommendations to the Board with respect to compensation of non-employee directors; and
- Reviewing and approving corporate goals and objectives relevant to Chief Executive Officer compensation, evaluating the Chief Executive Officer's performance in light of those goals and objectives, and setting the Chief Executive Officer's compensation levels based on this evaluation.

When appropriate, the Compensation Committee may, in carrying out its responsibilities, form and delegate authority to subcommittees. The Chief Executive Officer plays a role in determining the compensation of our other executive officers by evaluating the performance of those executive officers. The Chief Executive Officer's evaluations are then reviewed by the Compensation Committee. This process leads to a recommendation for any changes in salary, bonus terms and equity awards, if any, based on performance, which recommendations are then reviewed and approved by the Compensation Committee.

The Compensation Committee has the authority, at the Company's expense, to select, retain, terminate and set the fees and other terms of the Company's relationship with any outside advisors who assist it in carrying out its responsibilities, including compensation consultants or independent legal counsel.

The Board has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee. The Compensation Committee consists of Scott Juda, Tim Schroeder and Kelly Ganjei. Tim Schroeder is the chairman of the Compensation Committee. The Board has affirmatively determined that each member of the Compensation Committee meets the additional independence criteria applicable to compensation committee members under SEC rules and the NASDAQ Stock Market.

**Nominating and Corporate Governance Committee**

The Nominating and Corporate Governance Committee, among other things, is responsible for:

- reviewing and assessing the development of the executive officers, and considering and making recommendations to the Board regarding promotion and succession issues;
- evaluating and reporting to the Board on the performance and effectiveness of the directors, committees, and the Board as a whole;
- working with the Board to determine the appropriate and desirable mix of characteristics, skills, expertise, and experience, including diversity considerations, for the full Board and each committee;
- annually presenting to the Board a list of individuals recommended to be nominated for election to the Board;
- reviewing, evaluating, and recommending changes to the Company's Corporate Governance Policies and Committee Charters;
- recommending to the Board individuals to be elected to fill vacancies and newly created directorships;

- overseeing the Company's compliance program, including the Code of Conduct; and
- overseeing and evaluating how the Company's corporate governance and legal and regulatory compliance policies and practices, including leadership, structure, and succession planning, may affect the Company's major risk exposures.



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The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee consists of Tim Schroeder, Scott Juda and Kelly Ganjei. Kelly Ganjei is the chairman of the Nominating and Corporate Governance Committee.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who own more than 10% of the issued and outstanding shares of our common stock to file reports of initial ownership of common stock and other equity securities and subsequent changes in that ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. During the year ended December 31, 2018, the Company's securities were not registered to file reports under Section 13 or 15(d) of Securities Exchange Act of 1934 and as such the Company's officers, directors and greater than 10% beneficial owners were not required to file reports under Section 16(a).

**ITEM 11. EXECUTIVE COMPENSATION**

The following table sets forth the compensation for our fiscal years ended December 31, 2018 and 2017 earned by or awarded to, as applicable, our principal executive officer, principal financial officer and our other most highly compensated executive officers as of December 31, 2018. In this Annual Report, we refer to such officers as our "Named Executive Officers."

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Awards ($) | Option Awards ($)[4] | Non-Equity Incentive Plan Compensation ($) | Nonqualified Deferred Compensation Earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| Raymond J. Tesi | 2018 | $ 120,000 | 0 | 0 | $ 2,557,847 | 0 | 0 | 0 | $ 2,677,847 |
| CEO/President | 2017 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| David J. Moss | 2018 | $ 120,000 | 0 | 0 | $ 2,557,847 | 0 | 0 | 0 | $ 2,677,847 |
| CFO | 2017 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mark Lowdell | 2018 | 0 | 0 | 0 | $ 2,557,847 | 0 | 0 | $ 72,000 | $ 2,629,847 |
| CSO | 2017 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |



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**Employment Agreements**

The Company and David Moss have entered into an employment agreement, dated January 1, 2018, pursuant to which Mr. Moss is serving as our Chief Financial Officer. Pursuant to the employment agreement, Mr. Moss is paid a salary of $120,000 per annum provided that if we raise gross proceeds of at least $5,000,000 from an offering then his salary shall increase to $250,000 per annum and if we receive gross proceeds of at least $12,000,000 then Mr. Moss' salary will increase to $350,000. Pursuant to the employment agreement if Mr. Moss is terminated without cause, or if he terminates his employment for good reason, (as those terms are defined in the employment agreement) we will be required to pay him a lump sum payment equal to one times the period of time Mr. Moss worked for us without compensation. This period began on September 1, 2015 and runs until the first compensation received under an employment agreement with we after completion of the public offering. In accordance with his employment agreement. Mr. Moss has been issued options to purchase 400,000 shares of our common stock at an exercise price of $7.80 per share, of which options to 133,333 shares of Common Stock shall vested immediately and the option to purchase the remaining 266,667 shares shall vest at the rate of 11,111 share per month over twenty-four months, subject to the conditions set forth in the option agreement.

The options were granted from our 2017 Stock Incentive Plan.

The Company and Raymond Tesi, MD, have entered into an employment agreement, dated January 1, 2018, pursuant to which Dr. Tesi is serving as our Chief Executive Officer and President. Pursuant to the employment agreement, Dr. Tesi is paid a salary of $120,000 per annum provided that we raise gross proceeds of at least $5,000,000 from an offering then his salary shall increase to $250,000 per annum and if we receive gross proceeds of at least $12,000,000 then Dr. Tesi's salary will increase to $350,000. Pursuant to the employment agreement if Dr. Tesi is terminated without cause, or if he terminates his employment for good reason, (as those terms are defined in the employment agreement) we will be required to pay him a lump sum payment equal to one times the period of time Dr. Tesi worked for the Company without compensation. This period began on September 1, 2015 and runs until the first compensation received under an employment agreement with we after completion of the public offering. Dr. Tesi has been issued options to purchase 400,000 shares of our common stock at an exercise price of $7.80 per share 133,333 shares of Common Stock shall vested immediately and the option to purchase the remaining 266,667 shares shall vest at the rate of 11,111 share per month over twenty-four months, subject to the conditions set forth in the option agreement.

The options were granted from our 2017 Stock Incentive Plan 133,333 shares of Common Stock shall vested immediately and the option to purchase the remaining 266,667 shares shall vest at the rate of 11,111 shares per month over twenty-four months, subject to the conditions set forth in the option agreement. The options were granted from our 2017 Stock Incentive Plan. The options were granted from our 2017 Stock Incentive Plan.

**Consulting Agreement**

The Company and Mark Lowdell, PhD, have entered into a consulting agreement, dated January 1, 2018, pursuant to which Dr. Lowdell is serving as our Chief Scientific Officer. Pursuant to the consulting agreement, Dr. Lowdell is paid fees of $72,000 per annum. Dr. Lowdell has been issued options to purchase 400,000 shares of our common stock at an exercise price of $7.80 per share which vest over twenty-four months, subject to the conditions set forth in the option agreement. The options were granted from our 2017 Stock Incentive Plan. The Consulting Agreement was amended in July 2018 to remove the reference that Dr. Lowdell would serve as the Chair of the Company's Scientific Advisory Board as the Company does not have a Scientific Advisory Board.

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**Outstanding Equity Awards at Fiscal Year End**

The following table summarizes the total outstanding equity awards as of December 31, 2018, for each Named Executive Officer:

**Outstanding Equity Awards at Fiscal Year End**

| | Option awards | | | | | Stock awards | | | |
|---|---|---|---|---|---|---|---|---|---|
| Name | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Equity incentive plan awards: Number of securities underlying unexercised unearned options (#) | Option exercise price ($) | Option expiration date | Number of shares or units of stock that have not vested (#) | Market value of shares of units of stock that have not vested ($) | Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#) | Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($) |
| Raymond J. Tesi | 266,667 | 133,333 | 0 | $ 7.80 | 1/1/28 | 0 | 0 | 0 | 0 |
| David Moss | 266,667 | 133,333 | 0 | $ 7.80 | 1/1/28 | 0 | 0 | 0 | 0 |
| Mark Lowdell | 200,000 | 200,000 | 0 | $ 7.80 | 1/1/28 | 0 | 0 | 0 | 0 |

**Director Compensation**

The following table shows the compensation earned by persons who served on our Board of Directors during the fiscal year ended December 31, 2018, who are not one of our Named Executive Officers.

| Name | Fees Earned or Paid in Cash ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Nonqualified Deferred Compensation Earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Tim Schroeder | 0 | 0 | 685,973 | 0 | 0 | 0 | 685,973 |
| J. Kelly Ganjei | 0 | 0 | 685,973 | 0 | 0 | 0 | 685,973 |
| Edgardo Baracchini | 0 | 0 | 685,973 | 0 | 0 | 0 | 685,973 |
| Scott Juda | 0 | 0 | 685,973 | 0 | 0 | 0 | 685,973 |

During 2018, Mr. Juda has been granted options to purchase 108,000 shares of our common stock at an exercise price of $7.80 per share, of which 3,000 options a month vest until the 108,000 options have vested subject to the conditions set forth in the option agreement between the Corporation and Mr. Juda. The options were granted from our 2017 Stock Incentive Plan.



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During 2018, Mr. Schroeder has been granted options to purchase 108,000 shares of the Company's common stock at an exercise price of $7.80 per share, of which 3,000 options a month vest until the 108,000 options have vested subject to the conditions set forth in the option agreement between the Corporation and Mr. Schroeder. The Options were granted from the Company's 2017 Stock Incentive Plan.

During 2018, Mr. Ganjei has been granted options to purchase 108,000 shares of the Company's common stock at an exercise price of $7.80 per share, of which 3,000 options a month vest until the 108,000 options have vested subject to the conditions set forth in the option agreement between the Corporation and Mr. Ganjei. The Options were granted from the Company's 2017 Stock Incentive Plan.

During 2018, Dr. Baracchini has been granted options to purchase 108,000 shares of the Company's common stock at an exercise price of $7.80 per share, of which 3,000 options a month vest until the 108,000 options have vested subject to the conditions set forth in the option agreement between the Corporation and Mr. Baracchini. The Options were granted from the Company's 2017 Stock Incentive Plan. Dr. Baracchini resigned from our board in August 2018.

**Equity Compensation Plan Information**

**Adoption of INmune Bio, Inc. 2017 Stock Incentive Plan**

On November 15, 2017, the Board approved the INmune Bio, Inc. 2017 Stock Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the interests of the Company and its stockholders by providing (i) officers and employees, (ii) advisors, and (iii) non-employee directors with appropriate incentives and rewards.

The 2017 Plan provides for the granting of stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. The 2017 Plan also provides for the granting of performance stock awards so that the Board may use performance criteria in establishing specific targets to be attained as a condition to the grant or vesting of awards under the 2017 Plan.

The 2017 Plan provides for the grant of stock awards to employees, directors and consultants of the Company and its affiliates

covering an aggregate of 1,700,000 shares of common stock, subject to adjustments in the event of certain changes to the Company's capitalization.

The common stock subject to the 2017 Plan may be unissued shares or reacquired shares, including shares purchased on the open market. If a stock award granted under the 2017 Plan is forfeited, expires or is canceled or settled without issuance of common stock it shall not count against the maximum number of shares that may be issued under the 2017 Plan.

The Board has broad discretion in making grants under the 2017 Plan and may make grants subject to such terms and conditions as determined by the Board or a duly appointed committee thereof. Grants under the 2017 Plan will be subject to the terms and conditions set forth in the document making the award, including, without limitation any applicable purchase price and provisions pursuant to which the grant may be forfeited.

The Board may terminate or amend the 2017 Plan at any time, except for certain actions that may not be taken without stockholder approval. The 2017 Plan is scheduled to terminate on November 15, 2027.



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**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 15, 2019 :

- each of our current directors and executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock.

Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Our calculation of the percentage of beneficial ownership is based on 9,740,261 shares of common stock outstanding as of March 31, 2019. We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under Rule 13d-3 of the Exchange Act of 1934, as amended (the "Exchange Act"), a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise has or shares: (i) voting power, which includes the power to vote or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person or persons, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person or persons (and only such person or persons) by reason of these acquisition rights.

| Name and Address(1) | Common Stock Owned | Number of Shares Exercisable Within 60 Days | Percentage of Common Stock |
|---|---|---|---|
| **Executive Officers and Directors** | | | |
| Raymond J. Tesi | 1,515,833 | 322,220 (1)(2) | 18.87% |
| David J. Moss | 1,205,417 | 322,220 (1)(3) | 15.68% |
| Mark Lowdell | 1,503,333 | 283,322 (1)(4) | 18.34% |
| Tim Schroeder | 166,667 | 42,000 (5) | 2.14% |
| J. Kelly Ganjei | - | 42,000 (6) | *% |
| David Szymkowski | 1,585,000 | 42,000 (7) | 16.70% |
| Scott Juda, JD | 25,000 | 42,000 (10) | *% |
| **Officers and Directors as a group (7 individuals)** | 5,976,250 | 1,095,762 | 72.86% |
| | | | |
| **Beneficial owners of more than 5%** | | | |
| Toucan Capital Fund III (8) | 700,000 | | 7.2% |
| Xencor Inc. (9) | 1,585,000 | | 16.27% |

_____

* Less than 1%.

1 Except as otherwise indicated, the address of each beneficial owner is INmune Bio Inc., 1224 Prospect Street, Suite 150, La Jolla, CA 92037.

2 Consists of (i) 1,515,833 shares of common stock, and (ii) 322,220 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

3 Consists of (i) 1,205,417 shares of common stock, and (ii) 322,220 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

4 Consists of (i) 1,503,333 shares of common stock, and (ii) 283,322 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

5 The shares of the Company's common stock are held by CTI Holdings, a company of which Mr. Schroeder is the majority shareholder. Consists of (i) 166,667 shares of common stock, and (ii) 42,000 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

6 Consists of 42,000 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

7 The shares of the Company's common stock are held by Xencor, Inc. Consists of (i) 1,585,000 shares of common stock held by Xencor, Inc., and (ii) 42,000 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

8 Linda Powers of Toucan Capital Fund III and has voting and investment control of the shares of the Company's held by Toucan Capital Fund III, 4800 Montgomery Lane, Suite 801, Bethesda, MD 20814.

9 David Szymkowski of Xencor, Inc. and has voting and investment control of the shares common stock held by Xencor Inc. 111 W Lemon Avenue, Monrovia, CA 91016.

10 Consists of (i) 25,000 shares of common stock and (ii) 42,000 shares that may be acquired pursuant to the exercise of stock options within 60 days of March 31, 2019.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The following is a description of the transactions and series of similar transactions, since January 1, 2016, that we were a participant or will be a participant, in which:

- transactions in which the amount involved exceeds the lesser of $120,000 or one percent of the average of the smaller reporting company's total assets at year-end for the last two completed fiscal years; and

- any of our directors, executive officers, holders of more than 5% of our capital stock (which we refer to as "5% stockholders") or any member of their immediate family had or will have a direct or indirect material interest, other than compensation arrangements with directors and executive officers.

*License Agreement with Immune Ventures, LLC*

On October 29, 2015, we entered into an exclusive license agreement with Immune Ventures, LLC, owner of all of the rights related to our principal patent (the "License Agreement"). Pursuant to the License Agreement, we were granted exclusive worldwide rights to the patents, including rights to incorporate any improvements or additions to the patents that may be developed in the future. In consideration for the patent rights, we agreed to the following milestone payments (of which none have been met as of December 31, 2018):

| | |
|---|---|
| Each Phase I initiation | $ 25,000 |
| Each Phase II initiation | $ 250,000 |
| Each Phase III initiation | $ 350,000 |
| Each NDA/EMA filing | $ 1,000,000 |
| Each NDA/EMA awarded | $ 9,000,000 |

In addition, we agreed to pay the licensor a royalty of 1% of net sales during the life of each patent granted to us derived from the license. Immune Ventures, LLC is owned by Raymond J Tesi, our President and a member of our Board of Directors, David Moss, our Chief Financial Officer, Treasurer and Secretory, and Mark Lowdell our Chief Scientific Officer.

*License Agreement with Xencor, Inc.*

On October 3, 2017, we entered into a license agreement with Xencor, Inc., which has discovered and developed a proprietary biological molecule that inhibits soluble tumor necrosis factor.

Pursuant to the license agreement, Xencor granted us an exclusive worldwide, royalty-bearing license in licensed patent rights, licensed know-how and licensed materials (as defined in the license agreement) to make, develop, use, sell and import any pharmaceutical product that comprises, contains, or incorporates Xencor's proprietary protein known as "XPRO1595" that inhibits soluble tumor necrosis factor (or all modifications, formulations and variants of the licensed protein that specifically bind soluble tumor necrosis factor) alone or in combination with one or more active ingredients, in any dosage or formulation. In connection with the license agreement, we paid Xencor a one-time non-creditable and non-refundable fee of $100,000 and agreed to issue Xencor 1,585,000 shares of our common stock equal to 19% of our fully-diluted shares at that time. We also issued warrants to Xencor which are discussed below.





We also agreed to pay Xencor a royalty of 5% of all Licensed Products in a given calendar year, which are payable on a country-by-country and Licensed Product by Licensed Product basis until the date that is the later of (a) the expiration of the last to expire valid claim covering any pharmaceutical product that contains, comprises, or incorporates Xencor's proprietary protein known as XPRO1595 alone or in combination with one or more active ingredients, in any dosage or formulation ("Licensed Product") in such country or (b) ten years following the first sale to a third party of the Licensed Product in such country.

Under the license agreement, the Company also agreed to pay Xencor a percentage of any sublicensing revenue that it receives equal to (i) 60% of sublicensing revenue received in respect of any sublicense granted prior to initiation of a Phase 1 clinical trial of a Licensed Product in the applications for the treatment of disease in humans (the "Field"); (ii) 30% of sublicensing revenue received in respect of any sublicense granted on or after initiation of a Phase 1 clinical trial of a Licensed Product in the Field and prior to initiation of a Phase 2 clinical trial of a Licensed Product in the Field; (iii) 15% of sublicensing revenue received in respect of any sublicense granted on or after initiation of a Phase 2 clinical trial of a Licensed Product in the Field and prior to initiation of a Phase 3 clinical trial of a Licensed Product in the Field; (iv) 10% of sublicensing revenue received in respect of any sublicense granted on or after initiation of a Phase 3 clinical trial of a Licensed Product in the Field and prior filing of the first NDA application for any Licensed Product in the Field; and (v) 5% of sublicensing revenue received in respect of any sublicense granted on or after the approval of the first NDA application for any Licensed Product in the Field. Initiation of a clinical trial means dosing of a first patient in said clinical trial.

A valid claim is an issued, unexpired or pending claim with the patent rights that Xencor controls as of October 3, 2017 which patent rights are necessary to make, develop, use, sell, have sold, offer for sale and import a Licensed Product in the Field or the Product Patent Rights, which claim has not lapsed, been abandoned, been revoked or been held to be unpatentable, invalid or unenforceable by a final judgment of a court or other governmental agency or competent jurisdiction from which no appeal can be or is taken within the time allowed for appeal and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise. Product Patent Rights shall mean any and all our patent rights that are necessary to make, develop, use, sell, have sold, offer for sale and import a Licensed Product in the Field, including any improvements or patent rights directed to the Licensed Product. Either party may terminate the license agreement upon 60 days' (10 days for any payment default) prior written notice to the other party after the breach of any material provision of the agreement by the other party if the breaching party has not cured the breach within the 60-day period (10-day period for any payment default) following written notice of termination by the non-breaching party. We can terminate the agreement upon 180 days prior written notice to Xencor. Xencor may terminate the agreement in its entirety or with respect to any specific Licensed Product upon written notice in the event that we contest, oppose or challenge or assist any party in contesting, opposing or challenging, Xencor's ownership of, or the enforceability or validity of the patent rights that Xencor controls as of October 3, 2017 which Patent Rights are necessary to make develop, use, sell, have sold, offered for sale and import a Licensed Product in the Field. Either party may terminate the Agreement upon written notice to the other party upon or after the insolvency, bankruptcy, dissolution or winding up of such other party or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party or the initiation of proceedings in voluntary or involuntary bankruptcy which proceeding or action remains undismissed or unstayed for a period of more than 60 days.

In connection with the License Agreement, we entered into a stock issuance agreement with Xencor pursuant to which we agreed to issue Xencor 1,585,000 shares of our common stock, and an option to purchase up to an additional number of shares of common stock that shall equal 10% of the fully diluted company shares. The fully diluted company shares includes the aggregate number of (a) shares of common stock outstanding, plus (b) the number of shares of common stock issuable upon the conversion of all shares of outstanding preferred stock and convertible debt of the Company plus (c) the number of shares of Common Stock issuable upon conversion or exercise, as the case may be, of

all issued and outstanding securities of the Company convertible into, exercisable for, or exchangeable for, directly or indirectly, shares of Common Stock outstanding at such time, including but not limited to, issued and outstanding options and warrants to purchase Common Stock and disregarding any vesting restrictions or similar provisions. The aggregate purchase price for the full exercise of the option is $10,000,000 which purchase price shall be pro-rated for any partial exercise of the Option. In August 2018, we entered into a First Amendment to Stock Issuance Agreement. Pursuant to the amendment, the purchase price for the additional shares may only be paid by cash.



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In connection with the stock issuance agreement, the Company, Xencor and more than 90% of shareholders as of September 30, 2017 ("Key Holders") entered into a voting agreement. Pursuant to the voting agreement, Xencor and the Key Holders agreed to vote their respective shares to vote one individual designated by the holder of a majority of Xencor's shares of the Company's common stock to our board of directors. The voting agreement shall continue in full force and effect through the earliest of the following dates, on which date it shall terminate in its entirety: (a) the date that the company has of a qualified offering, as defined in the issuance agreement; (b) ten (10) years from the date of this Agreement; (c) the date that we have received gross cash proceeds of not less than $40,000,000 and we become subject to the reporting requirements of the Securities Exchange Act of 1934 or the sale of all or substantially all our business to which the License Agreement relates whether by merger, sale of stock, sale of assets or otherwise; or (d) the date as of which the parties hereto terminate the voting agreement by written consent of the us and Xencor.

*Consulting Agreement with Unrelated Third Party Consultant*

On May 16, 2018 we entered into a consulting agreement with an unrelated third party consultant. Pursuant to the consultant agreement, the consultant will assist us with our corporate governance and assist us in complying with securities and exchange regulations regarding the filing of a listing application. The consultant will also assist us with activities related to its initial public offering including road show execution and will also assist us with our investor relations strategy development. The term of the consulting agreement is from April 24, 2018 to May 1, 2021 (the "Consulting Period"). In consideration of the consultant's services, we have a contractual obligation to the consultant over the time of the Consulting Period in the amount of $1,500,000. The aggregate fair value of these shares issues is $4,626,000 at their fair value of $7.71 per share. The consultant has agreed to take this compensation in the form of restricted shares of our common stock. We have agreed to convert the compensation of the services provided by the Consultant at a price of $2.50 per share and we will issue 600,000 restricted shares ("Compensation") of our common stock as of the date hereof, of which 200,000 shares were vested on the execution of the agreement, 200,000 shares shall be locked up for six months after the effective date of the registration statement and 200,000 shares shall be locked up for 10 months after the date of the offering.

***Short-term debt – related party***

On May 9, 2016, the Company received cash proceeds of $350,000 from the issuance of a convertible note to Novamune that matured on August 1, 2016, with a conversion rate of $1.50 per share, and an annual interest rate of 8%. On September 3, 2016, the maturity date was extended to March 3, 2017. During the year ended December 31, 2017, the convertible note was converted into 233,345 shares of common stock of the Company. Novamune is owned by a significant shareholder of the Company.

***Prepaid expense – related party***

At December 31, 2018 and 2017, the Company had prepaid expense of $0 and $158,504, respectively, paid to UCL Consultants Limited, a wholly owned subsidiary of the University of London, in connection with medical research performed on behalf of the Company. The Company's Chief Scientific and Manufacturing Officer is a professor at the University of London.

***Accounts payable and accrued liabilities – related parties***

At December 31, 2018 and 2017, the Company owed Advent Bioservices $0 and $173,314, respectively, for medical research provided on behalf of the Company. Advent Bioservices is owned by a significant shareholder of the Company. At December 31, 2018 and 2017, the Company owed UCL Consultants Limited $9,020 and $0, respectively, in connection with medical research performed on behalf of the Company.



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**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

*Audit Fees*

The aggregate fees billed to us by our principal independent public accountant for services rendered for the years ended December 31, 2018 and 2017, are set forth in the table below:

| Fee Category | For the Year Ended December 31, 2018 | For the Year Ended December 31, 2017 |
|---|---|---|
| Audit fees (1) | | |
| GBH CPAs PC | $ 67,460 | $ 68,345 |
| Marcum LLP | 39,297 | - |
| Audit-related fees (2) | 11,900 | - |
| Tax fees | - | - |
| All other fees (4) | - | - |
| Total fees | $ 118,657 | $ 68,345 |

(1) Audit fees consist of fees incurred for professional services rendered for the audit of consolidated financial statements, for reviews of our interim consolidated financial statements included in our quarterly reports on Forms 10-Q and for services that are normally provided in connection with statutory or regulatory filings or engagements. Includes professional services performed for filing of the Company's registration statement on Form S-1 and for the Company's equity offerings.

(2) Audit-related fees consist of fees billed for professional services that are reasonably related to the performance of the audit or review of our consolidated financial statements, but are not reported under "Audit fees."

(3) Tax fees consist of fees billed for professional services relating to tax compliance, tax planning, and tax advice.

(4) All other fees consist of fees billed for all other services.

*Audit Committee's Pre-Approval Practice*

On August 5, 2018, we accepted the resignation of GBH CPAs, PC ("GBH") and engaged Marcum LLP as its independent registered public accountants. This change occurred in connection with GBH, the Company's prior independent public accountants, resigning as a result of GBH combining its practice with Marcum effective July 1, 2018. The engagement of Marcum has been approved by the Audit Committee of the Company's Board of Directors prior to its engagement.



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**PART IV**

**Item 15. Exhibits.**

| Exhibit No. | Description of Exhibit |
|---|---|
| 1.1 | Form of Placement Agent Agreement (Incorporated by reference to Exhibit 1.1 to the Registration Statement on Form S-1/A filed with the SEC on November 20, 2018). |
| 1.2 | Award Letter dated as of February 22, 2019 from the Alzheimer's Association to INmune Bio, Inc. (Incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the SEC on February 28, 2019) |
| 3.1 | Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 3.2 | Bylaws (Incorporated by reference to Exhibit 3.2 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 4.1 | Form of Registrant's common stock certificate (Incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A filed with the SEC on September 26, 2018). |
| 4.2 | Form of Placement Agent Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A filed with the SEC on September 26, 2018). |
| 10.1 | Form of Subscription Agreement (Incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.2 | License Agreement between INmune Bio, Inc. and Immune Ventures LLC (Incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.3 | Assignment and Assumption Agreement with Immune Ventures LLC (Incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.4 | Exclusive License Agreement by the University of Pittsburgh of the Common Wealth system of Higher Education and Immune Ventures LLC (Incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.5 | First Amendment to Exclusive License Agreement by and between the University of Pittsburgh of the Commonwealth system of Higher Education and Immune Ventures, LLC (Incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.6 | Joint Development Agreement between INmune Bio, Inc. and Novamune (Incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.7 | Material Transfer and License Agreement between Anthony Nolan Cord Blood Bank and Immune Bio International LTD. (Incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.8 | Employment Agreement between INmune Bio Inc. and Raymond Tesi (Incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.9 | Employment Agreement between INmune Bio Inc. and David Moss (Incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.10 | Consulting Agreement between INmune Bio Inc. and Mark Lowdell (Incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.11 | INmune Bio, Inc. 2017 Stock Incentive Plan (Incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |



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| | |
|---|---|
| 10.12 | Form of Incentive Option Agreement with employees (Incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.13 | Form of Incentive Option Agreement with non-employee directors (Incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.14 | Consultant Agreement between INmune Bio Inc. and Pacific Seaboard Investments Ltd. (Incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.15 | License Agreement between INMune Bio Inc. and Xencor, Inc. (Incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |

| | |
|---|---|
| 10.16 | Voting Agreement between INmune Bio Inc. and Xencor, Inc. (Incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.17 | Amendment to the Consultancy Agreement between INMune Bio Inc. and Mark Lowdell (Incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.18 | Form of Lock-up Agreement (Incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1/A filed with the SEC on October 29, 2018). |
| 10.19 | First Amendment to Stock Issuance Agreement (Incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018). |
| 10.20 | Form of Waiver of Registration Rights. (Incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1/A filed with the SEC on September 26, 2018). |
| 10.21 | Form of Subscription Agreement to be used in connection with the Best Efforts Offering (Incorporated by reference to the Registration Statement on Form S-1/A filed with the SEC on September 26, 2018). |
| 10.22 | Award Letter dated as of February 22, 2019 from the Alzheimer s Association to INmune Bio, Inc. (Incorporated by reference to the Current Report on Form 8-K filed with the SEC on February 28, 2019) |
| 21.1 | Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 filed with the SEC on August 30, 2018. |
| 31.1 | Certification of principal executive officer pursuant to Section 3.02 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of principal financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

**Item 16. Form 10-K Summary**

None.



*Table of Contents*

**SIGNATURES**

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

Dated: March 29, 2019

INMUNE BIO INC.
*/s/ Raymond J. Tesi, M.D.*
Raymond J. Tesi, M.D.
Chief Executive Officer
(principal executive officer)

Dated: March 29, 2019

*/s/ David Moss*
David Moss
Chief Financial Officer
(principal financial and accounting officer)

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

| Signature | Title | Date |
|---|---|---|
| */s/ Raymond J. Tesi, M.D.*<br>Raymond J. Tesi, M.D. | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 29, 2019 |
| */s/ David J. Moss*<br>David J. Moss | Chief Financial Officer, Treasurer, Secretary<br>*(Principal Financial and Accounting Officer)* | March 29, 2019 |
| */s/ Marl Lowdell, Ph D.*<br>Mark Lowdell, Ph.D. | Chief Scientific Officer | March 29, 2019 |
| */s/ Timothy Schroder*<br>Timothy Schroder | Director | March 29, 2019 |
| */s/ David Szymkowski*<br>David Szymkowski | Director | March 29, 2019 |

| | | |
|---|---|---|
| */s/ J. Kelly Ganjei*<br>J. Kelly Ganjei | Director | March 29, 2019 |
| */s/ Scott Juda, JD*<br>Scott Juda, JD | Director | March 29, 2019 |



EX-31.1 2 inmb_ex311.htm CERTIFICATION

**EXHIBIT 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE**
**SARBANES-OXLEY ACT OF 2002**

I, Raymond J. Tesi, certify that:

1. I have reviewed this Annual Report on Form 10-K of INmune Bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: March 29, 2019

By: */s/ Raymond J. Tesi, M.D.*
Raymond J. Tesi, M.D.
President, Chief Executive Officer and Director
*(Principal Executive Officer)*

EX-31.2 3 inmb_ex312.htm CERTIFICATION

**EXHIBIT 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**PURSUANT TO SECTION 302 OF THE**
**SARBANES-OXLEY ACT OF 2002**

I, David J. Moss, certify that:

1. I have reviewed this Annual Report on Form 10-K of INmune Bio, Inc.;

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

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

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

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

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under

our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Dated: March 29, 2019

By: */s/ David J. Moss*
David J. Moss
Chief Financial Officer, Treasurer, Secretary
*(Principal Financial and Accounting Officer)*

EX-32.1 4 inmb_ex321.htm CERTIFICATION

**EXHIBIT 32.1**

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

In connection with the Annual Report of INmune Bio, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raymond J. Tesi, Chief Executive Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 29, 2019

By: */s/ Raymond J. Tesi, M.D.*
Raymond J. Tesi, M.D.
President, Chief Executive Officer, and Director
*(Principal Executive Officer)*

EX-32.2 5 inmb_ex322.htm CERTIFICATION

**EXHIBIT 32.2**

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

In connection with the Annual Report of INmune Bio, Inc. (the "Company") on Form 10-K for the fiscal ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), I, David J. Moss, Chief Financial Officer of the Company, certify to my knowledge and in my capacity, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 29, 2019

By: */s/ David J. Moss*
David J. Moss
Chief Financial Officer, Treasurer and Secretary
*(Principal Financial and Accounting Officer)*

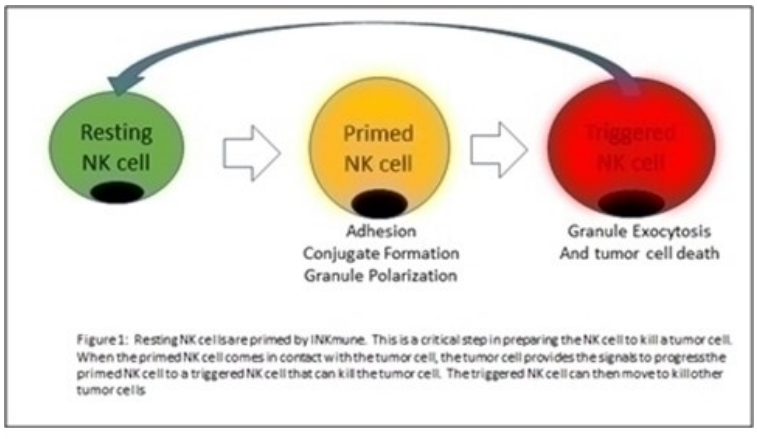



Figure 1: Resting NK cells are primed by INKmune. This is a critical step in preparing the NK cell to kill a tumor cell. When the primed NK cell comes in contact with the tumor cell, the tumor cell provides the signals to progress the primed NK cell to a triggered NK cell that can kill the tumor cell. The triggered NK cell can then move to kill other tumor cells

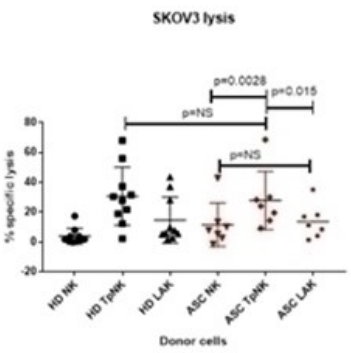



Figure 2: INKmune primed NK cells kill SKOV3, a NK resistant ovarian cancer cell line, in an *in vitro* tumor killing assay. NK cells from healthy donors (HD NK) or patient NK cells isolated from ovarian patient ascites (ASC NK) do not kill SKOV3. After priming NK cells with INKmune, healthy donor (HD TpNK) and patient (ASC TpNK) NK cells kill significantly more SKOV3 cells than unprimed NK cells from healthy donors (HD NK) or patients (ASC NK). IL2 primed NK cells from healthy donor (HD LAK) or ovarian cancer patient ascites (ASC LAK) do not kill SKOV3 tumor cells. INKmune primed NK cells from patients (ASC TpNK) and from healthy donors (HD TpNK) are equally effective in killing SKOV3 tumor cells.

Figure 3: INB03 does not cause immunosuppression, a known safety side-effect of currently available non-selective TNF inhibitors, because INB03 does not block transmembrane TNF. In this model, CBL/6mice are given a sublethal dose of Listeria then have TNF function manipulated by genetic knock-out or by pharmacologic treatment. Normal all animals survive the sublethal infection (red). Animals with a double soluble and transmembrane knock-out die quickly (gray). Mice with a single gene knock-out (tmNF KI, have) functional trans-membrane TNF all survive (green). The pharmaceutical experiment mimics the results of the genetic KO experiment. Double blockade of soluble and transmembrane TNF with etanercept causes animals to die quickly (blue) while animals treated with INB03 that neutralizes soluble TNF while preserving transmembrane TNF function all survive (black). This experiment demonstrates that the cause of immunosuppression seen with currently available non-selective TNF inhibitors is an off-target effect of trans-membrane TNF blockade and that INB03 does not cause immuno-suppression.

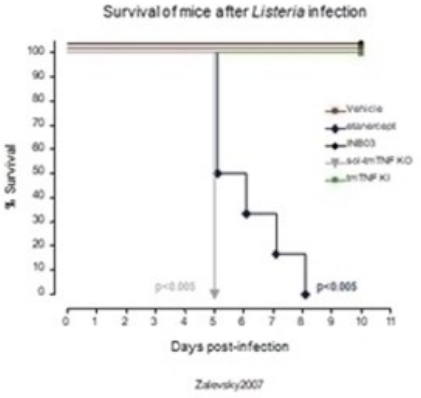



Figure 4: INB03 is a bioengineered 27 kDal protein that is identical to the monomeric subunit that forms the TNF homotrimer. There are 6 amino acid mutations engineered into the protein, 3 are on the surface of the protein (red). Two of the protein mutations are in the binding site to prevent binding to TNF receptor. The third mutation is to allow efficient PEGylation with a linear 10 kDal PEG that improves half-life to 18 hours. The protein is produced in E.coli.

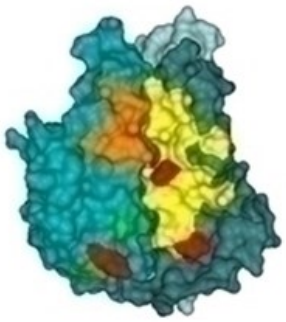


Figure 5: INB03 is a novel dominant-negative TNF inhibitor that is very different from currently approved non-selective TNF inhibitor. TNF is a homo-trimer that binds the TNF receptor. INB03 (brown ovals with handlebars) is a mutated TNF that freely exchanges with soluble TNF (top panel) to form a heterotrimer that can not bind to TNF receptors. INB03 can not effect trans-membrane TNF because the TNF monomers are anchored to the cell membrane (lower panel). The unique mechanism of action allows INB03 to be highly selective inhibitor of soluble TNF. Currently available TNF inhibitors block both soluble and transmembrane TNF. These non-selective TNF inhibitors have an efficacy and safety profile that is different from INB03. Also, soluble TNF can have effects on cells distant from the source of the cytokine. Transmembrane TNF, because it is protein bound requires cell-cell contact to have its effects.

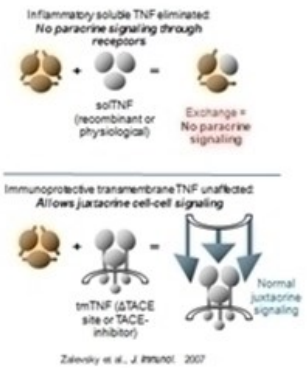
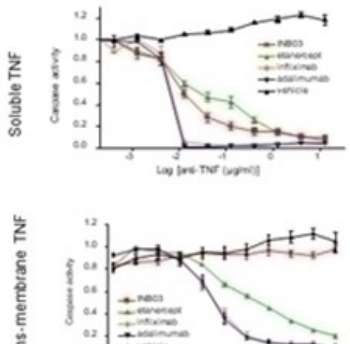
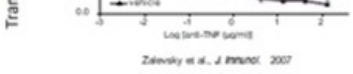



Figure 6: INB03 is a Dominant-Negative TNF inhibitor that block soluble TNF without affecting transmembrane TNF. This gives INB03 a different safety and efficacy profile from existing non-selective TNF inhibitors. The specificity of INB03 comparted to 3 currently approved non-selective TNF inhibitors is shown in the figure. INB03, etanercept, infliximab and adalimumab all inhibit soluble TNF (top figure). INB03 does not inhibit trans-membrane TNF while , etanercept, infliximab and adalimumab do inhibit trans-membrane TNF. The caspase activity assay is a well validated assay to demonstrate TNF function.






Zalevsky et al., *J. Immunol.* 2007