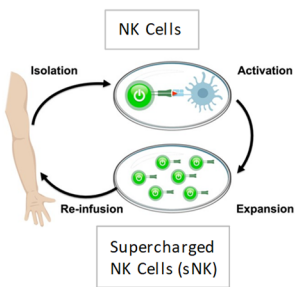




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NK101 - SUPERCHARGED NK CELLS



Proprietary activation method based on Dr. Jewett's research (the Company's co-founder and Chief Scientific Advisor)


Activation method produces NK101 cells (sNK cells):

- More potent NK cells
- Enhance cytotoxic function
- Increase secretion of IFN to induce differentiation of cancer stem cells
- Decrease the likelihood of tumor regeneration and metastasis
- More robust to better withstand tumor microenvironment.


NK101 HUMAN TRIAL RESULTS - PATIENT 1

Inferior Right External Iliac Lymph Node Tumor Size

Baseline Pre-Infusion (27 x 16 mm)



70 Days Post-Infusion 16 x 8 mm (70% Reduction)



Following a single infusion of NK101, the treating oncologist has stated that the patient is showing early signs of partial remission and immune restoration.

COMPANY DESCRIPTION

NKore Biotherapeutics, LLC (“NKore” or “the Company”) is a cellular-based biotherapeutics company focused on the early detection, prevention, and treatment of cancer. The Company’s technology is based on a proprietary method of activating **natural killer (NK)† cells**, creating Supercharged Natural Killer (sNK) cells used as a novel oncology **immunotherapy** platform. NKore’s proprietary activation method enhances NK cells’ overall effectiveness, making them significantly more potent (i.e., they are more **cytotoxic** to the cancer cells), while reducing the likelihood of tumor regeneration and metastasis. The technology was developed by Dr. Anahid Jewett, the Company’s co-founder and Chief Scientific Advisor. Based on positive preclinical results, the Company believes that Dr. Jewett’s 30-plus years of researching NK cell function has resulted in the development of a novel and effective cancer immunotherapy. NKore’s current focus is to translate and replicate the positive preclinical results into human clinical trials and achieve marketing approval. To support its immunotherapy initiative, NKore also intends to commercialize a proprietary companion cell-based diagnostic screening platform to monitor the patient’s immune function to measure response to therapy and assist physicians in the development of better personalized treatment plans.

KEY POINTS

- Working with Dr. Jewett, NKore has developed NK101, a non-engineered cellular immunotherapy for the treatment of both solid tumors and hematologic malignancies.
- Preclinical studies have demonstrated NK101’s ability to stop or reverse disease progression as well as to reduce the metastatic potential in preclinical models for many forms of cancer, including **glioblastoma**, pancreatic, melanoma, oral, lung, and ovarian cancer, as well as hematologic malignancies.
- NKore has initiated human clinical use outside the U.S. using NK101 as a palliative treatment option for patients with metastatic or unresectable cancers. Initial clinical use in Cancun, Mexico, includes two patients to demonstrate the safety of NK101. With additional clinical data, the Company intends to file an **Investigational New Drug (IND)** application with the FDA seeking approval to commence clinical trials in the U.S.
- NK101’s safety profile appears excellent, with neither patient experiencing any adverse side effects or discomfort after therapy.
- At 60 days post-infusion, Patient 1 (a 64-year-old male diagnosed with a form of **non-Hodgkin’s lymphoma** and presenting with a genetic mutation that limits his ability to respond to conventional therapy) saw a 75% reduction in tumor cell infiltration in the bone marrow, as well as a significant reduction in the size of enlarged lymph nodes.
- Early results in Patient 2, an 11-year-old girl diagnosed with an incurable **Optic Pathway Glioma** brain tumor, demonstrate NK101’s positive safety profile even in a pediatric patient.
- Since formation, NKore has completed funding activities totaling approximately \$3.2 million.

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Executive Overview

NKore Biotherapeutics, LLC (“NKore” or “the Company”) is a cellular-based biotherapeutics company focused on the early detection, prevention, and treatment of cancer. The Company utilizes a proprietary approach to activate or “supercharge” natural killer (NK) cells for the clinical development and commercialization of a novel immunotherapy to treat cancer. To support its immunotherapy initiative, NKore also intends to commercialize a proprietary companion cell-based diagnostic screening platform. Figure 1 provides an overview of NKore’s areas of focus. Using its innovative immunotherapy technology, NKore is seeking to position itself at the forefront of the detection, prevention, and treatment of cancer, to significantly improve patient outcomes.

Figure 1
 NKORE FOCUS

NK Cell Cancer Immunotherapy	NK Cell Diagnostics
<p>NK101-Supercharged NK (sNK) Cells™</p>	<p>NK Cell Function-based Diagnostic Tests</p>
<p>Supercharged NK (sNK) Cell™ technology for the development of novel cancer immunotherapy options</p>	<p>NKore's proprietary cell-based diagnostic screening platform to assess immune function at a cellular level and measure response to therapy</p>

Source: Nkore BioTherapeutics, LLC.

NKore’s technology platform is based on a proprietary method of activating NK cells, creating Supercharged Natural Killer (sNK) cells, to significantly enhance their cytotoxic function and overall effectiveness in treating and preventing cancer. The technology was developed by Dr. Anahid Jewett, the Director of the Tumor Immunology Laboratory in the Division of Oral Biology and Medicine at UCLA and the Company’s co-founder and Chief Scientific Advisor (biography on pages 9-10). The Company believes that Dr. Jewett’s 30-plus years researching NK cell function has resulted in the development of a novel and effective cancer immunotherapy for the treatment of both solid tumors and hematologic malignancies. NKore’s current focus is to translate the positive preclinical results into human clinical trials and achieve marketing approval.

Cancer and NK Cell Immunotherapy

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020 derived from 19.3 million new cases (Source: World Health Organization). In the U.S., cancer is the second leading cause of death, with over 1.9 million new cancer cases expected in 2023, resulting in approximately 610,000 deaths. The oncology market is one of the largest pharmaceutical markets, forecasted to reach \$375 billion in 2027, up from \$196 billion in 2022 (Source: IQVIA’s *Global Oncology Trends 2023, Outlook to 2027, 2023*).

For decades, the main treatment options for cancer patients following surgery have been chemotherapy and radiotherapy. However, these options are associated with severe toxicities, reduced physical strength, and impaired immune response, which can lead to cancer recurrence as well as metastasis of the remaining tumor cells. To counteract these adverse effects, researchers are developing new cancer therapies with improved efficacies and more favorable safety profiles. One prominent method, called immunotherapy, utilizes the body’s immune system to fight the disease. In particular, cell-based immunotherapy (also known as adoptive cell therapy) uses the immune system’s own cells as the therapeutic agent. In cell-based immunotherapy, the selected immune cells are first removed from either the patient or a healthy human donor, then activated or modified to enhance their cancer-fighting capabilities, expanded, and finally re-infused into the patient.

Interest in adoptive cell therapy has significantly increased due to the early clinical successes of autologous **chimeric antigen receptor T lymphocyte (CAR-T) therapy**—where **T-cells** are extracted from the patient and genetically engineered before being re-infused—the first cell therapy to enter commercialization. However, CAR-T's complex and costly manufacturing process, the requirement of a patient's own cells as a source material (with patients heavily pretreated and with compromised immune systems), and its related toxicities have limited the applications for this technology. To overcome these issues, natural killer (NK) cells are being explored as an alternative cell source for **allogeneic** cell therapies.

NK cells, part of the innate immune system, have an inherent ability to recognize and eliminate cancer cells. NK cells function as the body's natural defense mechanism, killing abnormal, mutated, or virally infected cells and detecting and controlling signs of cancer in the initial stages. Compared to other immunotherapies, NK cell therapy, specifically allogeneic NK cell therapy (which NKore is utilizing), has three key advantages in terms of efficacy, manufacturing, and safety: (1) NK cells do not need to be genetically engineered or modified to recognize cancer cells, resulting in a simplification of the complex, costly, and lengthy manufacturing process used for many other immunotherapies; (2) in allogeneic NK therapy, NK cells are harvested from healthy individuals with fully functioning immune systems that have not been compromised by cancer or toxic therapies; and (3) NK cell therapy provides a better safety profile compared to other forms of cancer treatment, such as chemotherapy, radiation, CAR-T therapy, and other immunotherapies.

NK Cells and Cancer

NK cells are critical in the fight against cancer. Due to their ability to identify and spontaneously kill cancer cells, NK cells play a dual role in the prevention and treatment of cancer. NK cells cytotoxic activity not only attacks infected and cancerous cells in the tumor, but also helps eliminate poorly differentiated **cancer stem cells (CSC)** and stem-like cells, playing a key role in the prevention of cancer recurrence and metastases.

CSCs are a subpopulation of tumor cells displaying self-renewal ability and multi-lineage differentiation, and their presence is recognized as a crucial factor contributing to tumor progression, recurrence, and metastasis. Conventional cancer treatments are often unable to target CSCs due to their highly resistant nature. Thus, novel treatment options that attack and/or help differentiate the CSC subpopulation (eradicating them and/or eliminating their self-renewal ability) appears to be a promising strategy for cancer treatment (Source: *Molecular Cancer*, Vol. 22 (171), 2023).

NK cells play a dual role in the elimination of CSCs. NK cells have been shown to selectively kill CSCs as well as eliminate circulating cancer cells with stem-like cell characteristics. In addition, NK cells are also capable of releasing cytokines and chemokines, including **gamma interferon (IFN- γ)** and **tumor necrosis factor alpha (TNF α)**, which can induce CSCs differentiation, resulting in their eradication and decreasing the possibility of recurrence and metastasis (Source: *Communications Biology*, Vol. 5 (436), 2022).

However, despite NK cells' key role in controlling cancer, the **tumor microenvironment (TME)** has been shown to suppress both the number and the function of NK cells, diminishing IFN- γ secretion, reducing cytotoxicity against cancer cells, and adversely influencing other anti-cancer processes (Source: *Cancers (Basel)*, Vol. 13(16): 4129, 2021). As the development and progression of cancer are correlated with the dysfunction of NK cells, the ability to enhance the function of NK cells to resist the negative effects of the TME through novel cell immunotherapy strategies could be the key for the development of more effective immunotherapy options.

NKore's Proprietary NK Cell Immunotherapy: NK101

NKore's technology platform is based on a proprietary method of activating and expanding allogeneic NK cells to create Supercharged Natural Killer (sNK) cells. The novel activation method makes the sNK cells significantly more potent by enhancing the cytotoxic function of primary NK cells and increasing the secretion of functional IFN- γ to induce the differentiation of those CSCs in the tumor microenvironment that avoid cell death. Inducing the differentiation of the surviving cancer stem cells that avoid cell death reduces the likelihood of tumor regeneration and metastasis. The differentiation of the CSCs also induces the expression of **MHC class I** and other receptors on the surface of the cancer stem cells to make them more susceptible to targeting and elimination by the patient's T-cells and B-cells. In addition to being more potent, NKore's activation method also makes the sNK cells more robust to allow them to better withstand the suppressive TME and survive longer in vivo.

Working with Dr. Jewett, NKore has developed NK101, a cellular-based immunotherapy that has proven effective in treating both solid tumors and hematologic malignancies in preclinical studies that have included over 350 humanized mice. These studies have demonstrated the ability to stop or reverse disease progression in many forms of cancer including pancreatic, melanoma, oral, breast and leukemia, among others, as well as restore immune function in some animals. Other in vitro preclinical studies have demonstrated the ability of the sNK cells to target and spontaneously kill other solid tumor cells, including glioblastoma and ovarian cancer cells.

NK cells belong to the innate lymphoid cell family and comprise 5% to 15% of peripheral white blood cells. These cells have two discreet functions: (1) to kill CSCs/poorly differentiated tumors (or other abnormal cells) in the body through cell mediated cytotoxicity; and (2) the secretion of IFN- γ and TNF α to induce the differentiation of those CSCs that avoid cell death. NK cells are known to be critical immune cells in the fight against cancer. However, the TME has been shown to suppress both the number and the function of NK cells.

To overcome this TME-driven impairment, Dr. Jewett developed a method to activate NK cells obtained from young healthy donors (allogeneic cells) to create NK101—supercharged NK cells (sNK)—for clinical use as a cellular-based immunotherapy. The activation method used to produce NK101, detailed on page 27, has been specifically developed to make the allogeneic NK cells more potent and more robust to enable the cells to withstand the suppressive TME. The proprietary activation method enhances the cytotoxic function of the sNKs, while increasing the secretion of functional IFN- γ to induce the differentiation of aggressive undifferentiated cancer stem and stem-like cells in the TME, making them more susceptible to other forms of cancer treatment, including chemotherapy, radiation therapy, and multiple forms of immunotherapy. NKore's proprietary activation method provides the following advantages:

- significant cell expansion potential;
- enhanced cytotoxic function;
- secretion of more IFN- γ and TNF- α to induce CSCs differentiation and reduce the metastatic potential of the tumor cells that avoid cell death; and
- more robust NK cells to better withstand the suppressive TME.

The proprietary NK101 production incorporates the collection of allogeneic NK cells from young healthy donors, then formulated by expanding and activating the NK cells in vitro using the proprietary method developed by Dr. Jewett. NK101 is formulated to be administered to patients via infusion therapy (IV drip) under the supervision of a treating physician.

NK101 Clinical Development

In preclinical studies, sNK cells have proven highly effective in targeting and lysing aggressive solid tumor cells and hematologic cancer cells. NK101 immunotherapy has been evaluated in preclinical models of pancreatic tumor cells, glioblastoma, ovarian cancer, as well as melanoma, lung cancer, breast cancer, and hematologic malignancies. Based on these preclinical studies, NKore believes that NK101 immunotherapy will prove effective in slowing or reversing the progression of disease and reducing the metastatic potential of the remaining tumor cells in many forms of cancer.

A sizable portion of the NK101 preclinical studies were conducted by Dr. Jewett using humanized-**bone marrow-liver-thymus (BLT) mice**, a mouse model developed to more closely replicate the human immune system. The BLT mouse model provides a powerful tool to study human immunology and immunotherapies at a cellular level. Overall, Dr. Jewett evaluated sNK cells in preclinical models that included over 350 BLT mice. Given the similarities to the human immune system, NKore believes that the use of this mouse model in the preclinical studies should increase the probability that the preclinical results can be translated into patients in human trials.

In other preclinical studies, Dr. Jewett has shown that the administration of the sNK cells increases the efficacy of some conventional therapies, such as chemotherapy and check point inhibitors. Accordingly, NKore believes that NK101 will prove to be an effective monotherapy in treating some forms of cancer, particularly when diagnosed at an early stage of disease progression, and as an integral part of a combinational therapeutic approach for other forms of cancer or when the cancer is diagnosed at more advanced stages. Given the volume of preclinical data collected by Dr. Jewett at UCLA, coupled with the unique safety profile of NK cell therapies generally, NKore's current focus is to try to translate the positive preclinical results into patients in a clinical setting outside the U.S., then seek Investigational New Drug (IND) approval through the U.S. Food and Drug Administration (FDA). NKore believes that the data that will be collected in connection with the clinical use outside the U.S. will facilitate future discussions with the FDA as part of the IND submission process.

NK101 Clinical Use (Cancun, Mexico)

NK101 has not been approved for clinical use in the U.S. NKore anticipates filing its pre-IND submission with the FDA in 2024 and, subject to the guidance received from the FDA as part of the pre-IND process, file the IND application for NK101 in 4Q 2024 or 2025. The approval of the IND application by the FDA is required before NKore can commence human clinical trials in the U.S.

As the Company seeks to translate the positive preclinical results into patients, and pending the approval of its IND application, NKore has commenced clinical use outside the U.S. The Company's efforts are being conducted in Cancun, Mexico, with a focus on the clinical use of NK101 as a palliative treatment option for patients with metastatic or unresectable cancers for which standard curative measures do not exist or are no longer effective.

Patients that have failed other treatment options may elect palliative treatment with NK101 at the Rehealth Clinic in Cancun, a licensed treatment facility with considerable experience administering cellular therapies and other forms of infusion therapy, including autologous NK cell therapies. NKore has also engaged a third-party clinical research organization (CRO) to track patient outcome data with respect to treatment. The Company's goal is to demonstrate the safety of NK101 as a palliative treatment option and use that safety data to support its IND application in an effort to obtain FDA approval to commence clinical trials in the U.S. In addition, promising efficacy data could allow the Company to seek accelerated regulatory review from the FDA as part of the IND submission process.

NK101 Clinical Data

NKore engaged a licensed cell-based contract manufacturer in Cancun, Mexico to collect and process allogeneic sNK cells from qualified donors. In October 2023, the contract manufacturer successfully completed the activation and expansion process under cGMP conditions to produce NK101 for clinical use. The Company believes that this confirms its ability to successfully transfer the technology from an academic laboratory at UCLA to a manufacturing facility using current Good Manufacturing Practices (cGMP) to produce clinical doses.

The produced sNK cells were used to treat the first two patients in Cancun, with the therapy commencing on December 5, 2023. The two patients selected were: (1) a 64-year-old male diagnosed with a form of non-Hodgkin's lymphoma (**Chronic Lymphocytic Leukemia [CLL]**) three years ago. Following the first round of chemotherapy, the patient was informed by his clinical team that he had a genetic mutation which limits his ability to respond to conventional therapy that took his prognosis from good to poor; and (2) Ms. Ryan's (NKore's co-founder and CCO) daughter Sophie, an 11-year-old girl who was diagnosed with an incurable Grade 1 Optic Pathway Glioma brain tumor when she was 8 months old. As described on pages 31-32, Sophie received her father's **interleukin-2 (IL-2)** activated NK cells, a therapy that is significantly less effective than NKore's sNK cells, with the tumor shrinking for 16 months post therapy. Despite this success, Sophie's tumor is still present.

Following infusion, the safety profile of NK101 cells appears to be excellent, with early indications of a positive immune response in the post-infusion blood tests. Neither patient experienced any adverse side effects or discomfort after receiving the therapy and no adverse safety events were reported.

Patient 1 Results

Patient 1 received a single infusion of approximately 350 million NK101 cells on December 5, 2023, with bloodwork showing a positive early immune response. The initial result looks promising—with multiple validated data points demonstrating NK101's ability to target and spontaneously kill the tumor cells that had infiltrated the bone marrow; reverse disease progression; and restore partial immune function. The early clinical data is consistent with Dr. Jewett's preclinical results.

Patient 1 **bone marrow aspirate** tests pre- and post-infusion indicated a 75% reduction in tumor cell infiltration in the bone marrow in the 60 days following the initial treatment, from 20% to 5%.

In addition, CT scans showed a significant decrease in the size of the enlarged lymph nodes in the abdomen, with the treating oncologist stating that the patient is showing early signs of partial remission and immune restoration. Use of NK101 also resulted in higher secretion of IFN- γ , linked to a positive immune response to cancer and increased cytotoxic activity of the activated NK cells.

Patient 2 Results

Patient 2 received a single infusion of approximately 100 million NK101 cells on December 5, 2023, with no adverse events or side effects resulting from therapy. Like Patient 1, blood draws following therapy show a positive immune response and a significant increase in cytotoxicity and IFN- γ release. While the first post-infusion MRI did not show a measurable reduction in the size of the tumor in the brain, the clinical team believes that due to the location and nature of the disease, observable changes to tumor mass will require additional time. Additional patient follow up, including a second post-infusion MRI scan, will be completed in the next 45 days.

Treatment of the first two patients is a significant milestone for NKore. With limited funding and a small team, the Company has been able to demonstrate the ability to transfer the cell activation and expansion process from a research laboratory to a cGMP manufacturing facility and, more importantly, confirm the safety profile of NK101 in patients. While more patient data is needed to confirm the clinical safety of NK101, the early data is positive and, absent an unexpected negative safety finding, it should allow NKore's to expand the clinical use as a palliative treatment option in Cancun. NKore will start the next production run in mid-April and should have product available for the treatment of the next cohort of cancer patients by late June.

NKore is currently working with its clinical and medical advisory team to confirm the patient selection criteria and disease states to be treated with the next cohort of patients. It is anticipated that the disease states will include more aggressive cancer types, such as pancreatic cancer or glioblastomas, for which sNK cells have shown effectiveness in preclinical testing.

Diagnostic Platform

In addition to the activation method for NK101, NKore's IP portfolio includes a companion cellular-based diagnostic screening platform to measure the cellular function of the immune system to assess the patient's response to therapy and assist clinicians develop better personalized treatment plans. When commercially available, NKore's screening tests will seek to evaluate the quality of immune function at a cellular level to establish a baseline to better predict or detect the early onset of disease and measure changes to immune function over time. The goal is to identify changes to immune function prior to the onset of disease to allow clinicians to intervene earlier and seek to restore immune function to prevent, not reverse, disease progression. If, as the Company believes, NK101 proves to have a unique safety profile and can function as a catalyst to restore immune function, its use as a monotherapy could then provide a novel interventional therapeutic approach to prevent or delay the onset of disease. For a patient that has a family history of cancer and DNA biomarkers that indicate the presence of circulating tumor cells in the body, testing and monitoring his or her immune function will be essential in developing early intervention strategies.

Corporate Information (Headquarters, Employees, and History)

NKore has its beginnings in the actual cancer treatment of one patient. Dr. Jewett first met Ms. Tracy Ryan (two of NKore's four co-founders) due to Ms. Ryan's daughter's (Sophie) incurable Grade 1 Optic Pathway Glioma brain tumor, which was diagnosed when she was 8 months old. Sophie failed seven chemotherapy treatments and clinical trials over a seven-year period, and her tumor had not shrunk in the 5-year period prior to her treatment with IL-2 activated NK cells.

Dr. Jewett agreed to help Sophie after her second brain surgery to debulk her tumor in 2018, when Sophie was 6 years old. At this time, Dr. Jewett took the opportunity to implant Sophie's live tissue into humanized mice to create a personalized animal model. In studying Sophie's immune function, Dr. Jewett found that she had no NK cells in her brain and, therefore, no innate defense against the proliferation of the tumor cells. Sophie's live tumor tissue, cerebrospinal fluid, and blood have been studied extensively by Dr. Jewett, which have led to additional scientific findings with respect to disease progression and its effect on immune function.

It was through this collaboration that they decided, together with Mr. Greg Brophy and Mr. Tim Brahm (biographies on pages 9-10, respectively), to form NKore in 2020 to capitalize on Dr. Jewett's NK cell expertise. NKore licensed Dr. Jewett's core suite of patents for both her sNK cells and her suite of diagnostics tests from UCLA.

The Company currently has three full-time employees and is headquartered in Germantown, TN. In addition, the Company uses third party consultants or advisors to outsource its finance, regulatory, manufacturing, and legal functions.

Company Leadership

Management

NKore’s management team (Figure 2) and advisory board (Figure 3, page 11)) consists of an impressive group of cell therapy experts, inventors, and scientists, holding dozens of patents and hundreds of publications between them.

Figure 2
 MANAGEMENT

Greg Brophy	Co-Founder, Chief Executive Officer
Dr. Anahid Jewett	Co-Founder, Chief Scientific Advisor
Tracy Ryan	Co-Founder, Chief Communications Officer
Tim Brahm	Co-Founder, Director

Source: Nkore BioTherapeutics, LLC.

Greg Brophy, Co-Founder, Chief Executive Officer

Mr. Brophy is an experienced entrepreneur that has served in diverse operating roles throughout his career. Positions have included executive officer roles in two public companies (NYSE and NASDAQ), president of four distinct business groups, and head of business development with significant M&A and corporate finance experience. Prior to NKore, he served as CEO of Alafair Biosciences, a commercial-stage biomedical company developing a platform of biologic products based on its patented non-cell adhesive hydrogel technology. Prior to Alafair, Mr. Brophy served as president and CEO of BioD, a biomedical company in the regenerative medicine segment. BioD was sold to a public company in 2016. Previously, he served as president of Diagnostic Health Corporation, then a division of a public company and the fifth largest provider of independent outpatient diagnostic imaging services in the country. The division was sold to a private equity group. Mr. Brophy also served as President of the Clinical Tomograph Business Group, a \$350 million division of CTI Molecular Imaging Inc. CTI was the industry leader in positron emission tomography (PET) and PET/CT technology and was sold to Siemens AG in 2005. Prior to his corporate and entrepreneurial roles, Mr. Brophy was a corporate finance partner with Alston & Bird LLP in Atlanta, GA. He earned a B.S. degree in Electrical Engineering from the University of Notre Dame; a Juris Doctor from the University of Georgia School of Law; and an MBA from the MIT Sloan School of Management. He also served four years on active duty in the U.S. Army assigned to the 7th Infantry Division at Fort Ord, California.

Dr. Anahid Jewett, Co-Founder, Chief Scientific Advisor

Dr. Jewett is a professor and the Director of the Tumor Immunology Laboratory in the Division of Oral Biology and Medicine at UCLA and on the faculty of the Weintraub Center for Reconstructive Biotechnology, also at UCLA. She has membership in Jonsson Comprehensive Cancer Center (JCCC) and is a member of the UCLA Tumor Immunology subgroup. She is well-known nationally and internationally for her contribution to the field of NK biology, tumor immunology, and cancer immunotherapy. Dr. Jewett has received numerous honors and awards and holds memberships in professional organizations and societies. She has chaired important senate and non-senate committees at UCLA and for the University of California Regents and has been instrumental in shaping the graduate studies for the health professionals at UCLA. Dr. Jewett chairs and teaches several graduate level courses, and her laboratory is sought out by foreign and domestic scholars who spend years receiving training in NK studies.

In addition, Dr. Jewett serves on the editorial board of prestigious journals and has been a reviewer on the board of the National Institute of Health study sections. She holds patents and has given more than 200 invited lectures and presentations nationally and internationally and has published more than 100 high impact journal articles, reviews, commentaries, and book chapters in the field of cancer. She has research collaborations with investigators from China, Slovenia, Mexico, Poland, Germany, Thailand, Japan, Portugal, South Korea, and Sweden. Dr. Jewett has organized conferences on cancer immunity nationally and internationally. She has trained more than 150 graduate students and health professionals in her laboratory, many of whom are leaders in their respective institutions. Dr.

Jewett has served on review panels for grants from countries including England, France, the Netherlands, Qatar, Poland, and Israel. She has received grants, including from the NIH, for her studies.

One of Dr. Jewett's major contributions to science and NK cell biology was the identification, characterization, and the establishment of the concept of split energy in NK cells. Equally important was Dr. Jewett's discovery demonstrating that NK cells were important for the elimination, selection, and differentiation of cancer stem cells as well as healthy stem cells. Most recently she has identified, characterized, and patented a novel method to expand and activate or "supercharge" large numbers of NK cells for use as a cellular-based immunotherapy for the treatment of cancer. In addition, she has developed a formulation with probiotic bacteria to prevent and treat cancer patients in combination with the supercharged NK cells.

Tracy Ryan, Chief Communications Officer

Mrs. Ryan is an award-winning entrepreneur with over 27 years of experience with a focus on building globally recognized brands, raising capital, philanthropy, and pioneering research. As a public figure, she has traveled the world speaking in front of tens of thousands of people with her family's story having been covered by the top media outlets in the world. Her former companies include an award-winning Los Angeles-based marketing and graphic design agency, a globally recognized medical cannabis tincture company, and she is the founder of the 501c3 Saving Sophie named after her daughter. After her infant daughter Sophie's brain tumor diagnosis in 2013, she dedicated her life to helping patients who suffer from life altering ailments. Within a month of Sophie's diagnosis, the Ryans became cast members in film and TV star Ricki Lake's Netflix documentary "Weed the People" that followed the family for 6 years. After witnessing miracle after miracle in their own child who was using medical cannabis, they began working with thousands of patients to help guide them using plant medicine. In 2014 Mrs. Ryan launched a medical cannabis tincture company called CannaKids that became recognized worldwide for trailblazing the use of cannabis for life threatening diseases, with a focus on pediatrics. She sold CannaKids in 2020 to focus on NKore. Mrs. Ryan has collaborated extensively with medical researchers to find novel approaches when treating cancer patients, including renowned cannabis research scientist Dr. Dedi Meiri located at the Technion Institute in Israel. In 2018, she shifted her focus to the work of Dr. Anahid Jewett after Dr. Jewett agreed to study Sophie in the hopes of finding a cure for her incurable, low-grade brain tumor.

Tim Brahm, Co-Founder, Director

Mr. Brahm has over 30 years of experience in the human tissue biomedical engineering and medical device industries. He founded and operated the Mid-South Tissue Bank, a (501)(c) 3 not-for-profit corporation in 1991 and subsequently became a founding employee of Regeneration Technologies (RTIX), a publicly traded tissue bank that was spun out of the University of Florida. In 2004, Mr. Brahm founded United Tissue Services, which was acquired by Medtronic and is currently doing business as Spinal Graft Technologies with over a billion dollars in annual revenue. In 2009, Mr. Brahm founded BioD LLC, a manufacturer of cellular-based regenerative medicine products derived from placental tissues. BioD was acquired by Derma Sciences, a public company, in 2016 and Derma Sciences was subsequently acquired by Integra LifeSciences Corporation. Mr. Brahm serves on multiple biotech boards and is currently the CEO of a development stage company that is focused on miRNA analysis. Mr. Brahm is a prolific inventor with over thirty patents either pending or issued and actively supports the Brahm Chair of Excellence in Biomedical Engineering at the University of Florida. He attended the University of Memphis and holds degrees in Business Administration (BBA) and Biology (BS).

Advisory Board

Figure 3
 ADVISORS

Diederik Van der Reijt	Advisor
Jerry Chang	Advisor
Dr. Aneel Paulus	Medical Advisory Board
Dr. William Walsh	Medical Advisory Board
Dr. John Brophy	Medical Advisory Board
Dr. Anahid Jewett	Medical Advisory Board

Source: Nkore BioTherapeutics, LLC.

Diederik Van der Reijt

Mr. Van der Reijt is a seasoned entrepreneur and investor with over 20 years of experience in finance and startups. Starting his career as an options trader for an Amsterdam based firm, Mr. Van der Reijt quickly realized he wanted to work for himself. After relocating to Australia in 2006, he set up a high-frequency trading (HFT) firm together with his younger brother. Following the sale of a sizable portion of his stake, he returned to Europe and shifted his focus to his diverse portfolio of investments. After meeting Mrs. Ryan and Dr. Jewett, Mr. Van der Reijt became the first investor in NKore and has since served as a trusted advisor to the team since. With a track record of investing in over 25 companies and achieving numerous successful exits, he brings a depth of understanding to navigating the intricacies of the business landscape. Mr. Van der Reijt has successfully raised capital for both public and private enterprises across diverse sectors. While maintaining a sector-agnostic investment approach, he actively seeks impact investments capable of fostering positive change.

Jerry Chang, Advisor

Mr. Chang has over 20 years of experience in technology development and commercialization with key roles in operations, product development, quality assurance, and regulatory affairs. His career includes the invention, development and launch of novel surgical implants and sterilization platforms, aseptic formulation and production of biological materials, and quality oversight of manufacturing, validation and testing operations. Mr. Chang recently co-founded Samaritan Biologics, LLC, an organization focused on providing the best biologic products to end users with a commitment to availability and quality through independent distributors. Samaritan Biologics was also created with the intent to give back to the community, as 10% of all annual profits are donated to medically focused charities, such as the Juvenile Diabetes Research Foundation (JDRF). Mr. Chang joined BioD, LLC (now Integra LifeSciences: IART) in 2014 and served as the company’s Senior Vice-President of Business and Product Development until March 2019. He is also the co-founder and Managing Partner of Vigilant Bioservices, a biorepository and cold chain logistics services company. Previously, Mr. Chang served as Chief Operating Officer for Transplant Technologies of Texas which was recently acquired by Globus Medical (GMED), and he was a founding member and Director of Operations and Product Development at AxoGen Inc. (AXGN), a biotechnology company providing novel solutions to repair and regenerate peripheral nerves. Earlier, he worked for Regeneration Technologies (now RTI Surgical: RTIX) with increasing management responsibility in various important roles within this 400-person biotechnology company and its wholly owned subsidiaries. He began his technical career with Fuji Hunt Chemical Corporation and Abbott Laboratories. Mr. Chang is currently a member of the Upstate Carolina Angel Network and is an Affiliate Faculty Member and the External Advisory Board Chair at the J. Crayton Pruitt Family Department of Biomedical Engineering at the University of Florida.

Medical Advisory Board

Dr. Aneel Paulus

Dr. Paulus is a translational oncologist and entrepreneur with over 15 years of experience in cancer biology and clinical oncology research. He holds the position of Adjunct Associate Professor of Medicine at the Mayo Clinic School of Medicine and previously served as Director of Translational Research in Malignant B-cell Cancers and Co-Principal Investigator/Site Director for the B-cell cancer biorepository at the Jacksonville, Florida campus. He has published over 50 peer-reviewed scientific articles, contributed to several book chapters and presented at premier conferences on his work in preclinical-to-early clinical drug development of immunotherapy and small-molecule immunomodulatory drugs. Dr. Paulus also holds an adjunct teaching faculty position as Associate Professor of Medicine at University of Florida, Shands Hospital. He currently serves as Co-Founder and Chief Scientific Officer at Alpha2 Pharmaceuticals (Mayo Clinic spinoff) and CEO of WestEastern Health. His consulting experience spans Fortune 500 biopharma companies, such as GlaxoSmithkline, Bristol Myers Squibb, AstraZeneca, Janssen, Takeda as well as others such as Natera, Ascentage, Affimed AB, and Vivolux AB.

Dr. William K. Walsh, Chief Medical Officer

Dr. Walsh is a clinical oncologist in Bartlett, Tennessee (a suburb of Memphis) specializing in hematology and oncology at the Baptist Cancer Center and Baptist Memorial Hospital. He received an undergraduate degree from the University of Notre Dame and a medical degree from University of Tennessee Health Science Center College of Medicine. Dr. Walsh has been in practice for over 35 years.

Dr. John Brophy

Dr. Brophy is a West Point graduate, earning his medical degree from the Medical College of Georgia. He completed his neurological residency at Walter Reed Army Medical Center in 1989. His military experience and training included commander of a neurosurgical detachment during Operation Desert Shield-Desert Storm and the Army Ranger and Airborne courses. He served as Chief of Neurosurgery at the Naval Medical Center San Diego and held the rank of Lieutenant Colonel with twelve years on active duty. Dr. Brophy is a board-certified neurosurgeon who has been treating brain tumors with stereotactic radiosurgery using the Gamma Knife and Infini units for over 20 years. He is licensed to practice medicine in Tennessee, Mississippi, and Georgia.

Dr. Anahid Jewett

Biography on pages 9-10.

Milestones

Current Milestones

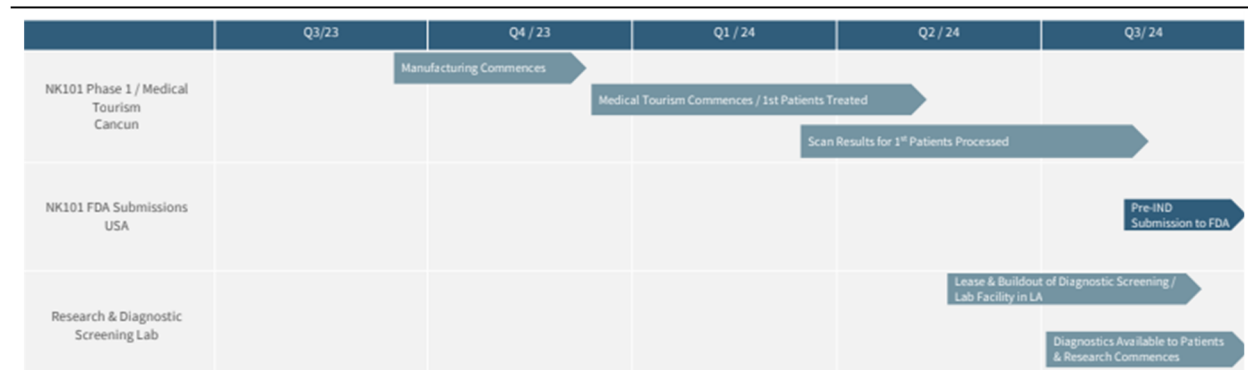
With limited funding and a small team, NKore has now demonstrated its ability to transfer the cell activation and expansion process, as well as the manufacturing of its proprietary NK101 sNK cells from a research lab to a cGMP manufacturing facility and, more importantly, confirm the safety profile of NK101 in patients. Specifically, NKore has achieved the following key milestones as it seeks to further advance the development of its proprietary drug pipeline to pursue FDA IND approval for the commencement of clinical trials in the U.S.:

- Completed a convertible note round totaling \$1,535,000, in addition to an initial equity funding round of \$1,674,926, for total capital raised of \$3,209,926.
- Completed the technology transfer to commence manufacturing of NK101 in Cancun, Mexico. Through the activities of a licensed cell-based contract manufacturer, the Company successfully completed the activation and expansion process under cGMP conditions to produce NK101 for clinical use.
- Commencing the next NK101 production run and should have product available for the treatment of the next cohort of cancer patients by late June.
- Successfully treated the first two patients in Cancun, Mexico, marking the Company’s first in-human clinical use and generating early positive patient safety data.

Potential Milestones

Moving forward, the Company has established objectives over the next 12 months as it seeks to achieve IND approval for use of NK101 in clinical trials in the U.S. These objectives include the compilation of the clinical data collected in connection with the treatment of the initial two patients in Cancun, as well as the expansion of NK101’s clinical use in Cancun as a palliative treatment option for patients with metastatic or unresectable cancers that have failed conventional therapies. Figure 4 displays the Company’s clinical development potential milestones.

Figure 4
 POTENTIAL MILESTONES



Source: Nkore BioTherapeutics, LLC.

Intellectual Property

NKore has licensed a portfolio of six pending patent families, including two issued patents from UCLA that includes the proprietary method of activating allogeneic or autologous Natural Killer (NK) cells developed by Dr. Anahid Jewett (biography on pages 9-10), a professor and the Director of the Tumor Immunology Laboratory in the Division of Oral Biology and Medicine at UCLA (and the Company's co-founder and Chief Scientific Advisor). The proprietary activation method enhances the cytotoxic function of the NK cells and increases the secretion of functional gamma interferon to induce the differentiation of cancer stem and stem-like cells in the tumor microenvironment. The activated NK cells are significantly more potent, i.e., they are more cytotoxic to the cancer stem and stem-like poorly differentiated aggressive tumors, and they secrete more functional gamma interferon to induce the differentiation of tumors that are chemo-resistant. In addition to being more potent, NKore's activation method also makes the activated NK cells more robust to allow them to better withstand the suppressive tumor microenvironment. The pending patents include a cellular-based diagnostic screening platform to measure the cellular function of the immune system to assess the clinical efficacy of treatment and develop better personalized patient treatment plans. In exchange for the patent rights, UCLA received an equity ownership interest in the Company and NKore is required to pay minimum annual royalties and milestones payments.

The two issued patents referenced above are U.S. Patent No. 9,763,982 entitled "Use of Peripheral Blood Mononuclear Cells to Trigger Differentiation of Mesenchymal Stem Cells and Osteoblasts" and Japanese Patent Application No.:2019-564396 entitled *Compositions And Methods For Activating NK Cells*. Both patents are part of NKore's foundational IP that covers, among other things, the proprietary method developed by Dr. Jewett to activate and expand the NK cells.

Figure 5 (page 15-17) provides an overview of the Company's patent portfolio.

Figure 5
IP PORTFOLIO

PATENT RIGHT
Use of NK Cells in Cancer Treatment or to Establish Tolerance of Transplanted Stem Cells

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2007-347-1	Use of NK Cells in Cancer Treatment or to Establish Tolerance of Transplanted Stem Cells	USA	6/29/2010	61/398,681	
2007-347-1	Use of NK Cells in Cancer Treatment or to Establish Tolerance of Transplanted Stem Cells	USA	3/3/2015	14/637,235	9,763,982

NONEXCLUSIVE PATENT RIGHT: UCLA CASE NO. 2017-183
Oral Composition Comprising Lactic Acid Bacteria for Regulating Immune Responses and Methods Related Thereto

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2017-183-1	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	USA	12/15/2016	62/434,837	Inactive
2017-183-2	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	PCT	12/15/2017	PCT/US17/66714	
2017-183-2	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	USA	12/15/2017	16/470,040	11,617,771
2017-183-2	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	China	12/15/2017	201780086167.6	
2017-183-2	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	Europe	12/15/2017	17881118.8	
2017-183-2	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	Hong Kong	12/15/2017	62020007412.3	
2017-183-3	Oral Compositions for Regulating Immune Responses and Methods Related Thereto	Hong Kong	4/3/2023	18/130,118	

EXCLUSIVE PATENT RIGHT: UCLA CASE NO. 2017-400
Osteoclast Activated Super-Charged NK Cells Preferentially and Rapidly Expand CD8+ T Cells from Cancer Patients and BLT Humanized Mice

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2017-400-1	Compositions and Methods for Activating NK Cells	USA	2/15/2017	62/459,397	Inactive
2017-400-2	Compositions and Methods for Activating NK Cells	PCT	2/15/2018	PCT/US2018/18389	
2017-400-2	Compositions and Methods for Activating NK Cells	USA	2/15/2018	16/486,123	
2017-400-2	Compositions and Methods for Activating NK Cells	Japan	2/15/2018	2019-564396	7374769
2017-400-2	Compositions and Methods for Activating NK Cells	Australia	2/15/2018	2018221745	
2017-400-2	Compositions and Methods for Activating NK Cells	Canada	2/15/2018	3059058	
2017-400-2	Compositions and Methods for Activating NK Cells	China	2/15/2018	201880025074.7	
2017-400-2	Compositions and Methods for Activating NK Cells	Europe	2/15/2018	18753992.9	
2017-400-2	Compositions and Methods for Activating NK Cells	South Korea	2/15/2018	10-2019-7026964	
2017-400-2	Compositions and Methods for Activating NK Cells	Singapore	2/15/2018	11201908472V	
2017-400-2	Compositions and Methods for Activating NK Cells	Japan	2/15/2018	2323-183162	
2017-400-3	Compositions and Methods for Activating NK Cells	USA	3/13/2023	18/209,148	

Source: Nkore BioTherapeutics, LLC.

Figure 5
 IP PORTFOLIO (Cont.)

EXCLUSIVE PATENT RIGHT
Compositions and Methods for Immunotherapies

2019-245-1	Compositions and Methods for Immunotherapies	USA	12/11/2018	62/778,189	
2019-245-2	Compositions and Methods for Immunotherapies	PCT	12/10/2019	PCT/US19/65381	
2019-245-2	Compositions and Methods for Immunotherapies	USA	12/10/2019	17/299,220	
2019-245-2	Compositions and Methods for Immunotherapies	Europe	12/10/2019	19895115.4	
2019-245-2	Compositions and Methods for Immunotherapies	Japan	12/10/2019	2021-532836	

EXCLUSIVE PATENT RIGHT: UCLA CASE NO. 2019-635
Unique NK Specific Tests to Determine the Expansion and Function of NK CELLS in Health and Disease

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2019-635-1	Systems and Methods for Evaluating NK Cells	USA	8/1/2019	62/881,626	Inactive
2019-635-2	Systems and Methods for Evaluating NK Cells	PCT	7/31/2020	PCT/US20/44431	
2019-635-2	Systems and Methods for Evaluating NK Cells	USA	7/31/2020	17/629,948	
2019-635-2	Systems and Methods for Evaluating NK Cells	Europe	7/31/2020	20847392.6	
2019-635-2	Systems and Methods for Evaluating NK Cells	India	7/31/2020	202127060985	
2019-635-2	Systems and Methods for Evaluating NK Cells	Japan	7/31/2020	2022-506351	

EXCLUSIVE PATENT RIGHT: UCLA CASE NO. 2019-700
Cannabis Prevents NK Inactivation in Cancer and Increases NK Function

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2019-700-1	Cannabis Prevents NK Inactivation In Cancer And Increases NK Function	USA	9/5/2019	62/896,573	Inactive
2019-700-2	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	USA	12/17/2019		
2019-700-3	Cannabis Prevents NK Inactivation In Cancer And Increases NK Function	USA	9/9/2020	63/076,126	
2019-700-4	Cannabis Prevents NK Inactivation In Cancer And Increases NK Function	PCT	9/9/2021	PCT/US21/49599	
2019-700-4	Cannabis Prevents NK Inactivation In Cancer And Increases NK Function	USA	9/9/2021	18/025,499	
2019-700-4	Cannabis Prevents NK Inactivation In Cancer And Increases NK Function	Europe	9/9/2021	21867571.8	

Source: Nkore BioTherapeutics, LLC.

Figure 5
 IP PORTFOLIO (Cont.)

EXCLUSIVE PATENT RIGHT: UCLA CASE NO. 2020-869
Cannabis Prevents NK Inactivation in Cancer and Increases NK Function

Tech Id	Title	Country	File Date	Serial No.	Patent No.
2020-869-1	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	USA	12/17/2019	62/949,364	
2020-869-2	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	USA	4/19/2021	62/176,581	
2020-869-3	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	USA	3/29/2022	17/707,134	
2020-869-3	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	PCT	3/29/2022	PCT/US22/22262	
2020-869-3	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	Canada	3/29/2022	3214348	
2020-869-3	Cannabis Limits Cancer Stem Cell Growth in Poorly Differentiated Cancers	Europe	3/29/2022	22792179	

Source: Nkore BioTherapeutics, LLC.

Core Story

NKore Biotherapeutics, LLC (“NKore” or “the Company”) is a cellular-based biotherapeutics company focused on the early detection, prevention, and treatment of cancer. The Company is seeking to combine a proprietary approach to activate or “supercharge” Natural Killer (NK) cells for the treatment of disease, with a companion diagnostic screening platform to measure the cellular function of the immune system to assess the clinical efficacy of treatment. The Company’s clinical development, underpinned by six patent families exclusively licensed from UCLA, are shown in Figure 6.

Figure 6
 NKORE RESEARCH AREAS

NK Cell Cancer Immunotherapy	NK Cell Diagnostics
<p>NK101-Supercharged NK (sNK) Cells™</p> <p>The use of proprietary Supercharged NK (sNK) Cell™ technology for the development of novel immunotherapy for the treatment of cancer</p>	<p>NK Cell Function-based Diagnostic Tests</p> <p>NKore's proprietary cell-based diagnostic screening platform to assess immune function at a cellular level and measure response to therapy</p>

Source: Nkore BioTherapeutics, LLC.

NKore’s technology platform is based on a proprietary method of activating and expanding donor NK cells to significantly enhance their cytotoxic effect on tumor cells. The technology was developed by Dr. Anahid Jewett, a professor and the Director of the Tumor Immunology Laboratory in the Division of Oral Biology and Medicine at UCLA and the Company’s co-founder and Chief Scientific Advisor (biography on pages 9-10).

The novel activation method makes NK cells significantly more potent (i.e., they are more cytotoxic to the cancer cells), while inducing the differentiation of cancer stem cells, thus reducing the likelihood of tumor regeneration and metastasis. In addition to being more potent, NKore’s activation method also makes the activated NK cells more robust and allows them to better withstand the suppressive tumor microenvironment.

Working with Dr. Jewett, NKore has developed NK101, a cellular-based immunotherapy that has proven effective in treating both solid tumors and hematologic malignancies in preclinical studies that have included over 350 humanized mice. These studies have demonstrated the ability to stop or reverse disease progression in many forms of cancer, including pancreatic, melanoma, oral, breast, and leukemia. Other in vitro preclinical studies have demonstrated the ability of the sNK cells to target and spontaneously kill other solid tumor cells, including glioblastoma and ovarian cancer cells.

Based on these preclinical results, the Company believes that Dr. Jewett’s 30-plus years researching NK cell function provides unique insight into the suppressive effect of the tumor microenvironment and has resulted in the development of a novel and effective cancer therapy. NKore’s current focus is to translate the positive preclinical results into patients, with an initial strategy to commence clinical use outside the U.S., then seek IND approval through the FDA.

To support its immunotherapy initiative, NKore is also seeking to commercialize a companion diagnostic screening platform to measure the cellular function of the immune system to assess the clinical efficacy of treatment. The Company believes that the companion diagnostics, once available, will provide treating physicians with the tools they need to better predict the early onset of disease to develop better personalized treatment plans for their patients.

NKORE'S BEGINNINGS

NKore has its beginnings in the actual cancer treatment of one patient. Dr. Jewett first met Ms. Tracy Ryan (two of NKore's four co-founders) due to Ms. Ryan's daughter's (Sophie) incurable Grade 1 Optic Pathway Glioma brain tumor, which was diagnosed when she was 8 months old. Although this form of cancer has a 90% survival rate, it has an over 85% recurrence rate, with the most common treatment option being chemotherapy. Ms. Ryan realized that little to no developments have been made over the last forty years for kids stricken by this form of cancer. Sophie failed seven chemotherapy treatments, two clinical trials, and her tumor did not shrink in the five-year period prior to her treatment with an IL-2 activated NK cell therapy described in more detail below.

Dr. Jewett and Ms. Ryan first met when Sophie was six years old due to Ms. Ryan's continuous efforts to find a cure for her young daughter's brain tumor. Dr. Jewett agreed to help Sophie after her second brain surgery to debulk her tumor in 2018, when Sophie was 6 years old. At this time, they took the opportunity to implant Sophie's live tumor tissue into humanized mice to create a personalized animal model. In studying Sophie's immune function, Dr. Jewett found that she had no NK cells in her brain and, therefore, no innate defense against the proliferation of the tumor cells. Sophie's live tumor tissue, CSF brain fluid, and blood have been studied extensively by Dr. Jewett, which have led to additional scientific findings with respect to disease progression and its effect on immune function.

It was through this collaboration that they decided, together with Mr. Greg Brophy and Mr. Tim Brahm (biographies on page 9-10, respectively), to form NKore in 2020 to capitalize on Dr. Jewett's NK cell expertise. NKore licensed Dr. Jewett's core suite of patents for both her sNK cell activation method and her suite of diagnostic screening tests.

In 2021, Sophie received two infusions of her father's IL2 activated NK cells which, although still based on Dr. Jewett's research, are different than NKore's NK101 sNK cell immunotherapy, and in preclinical research, much less potent. After 5 1/2 months post treatment, the tumor began to shrink and continued to shrink subsequently. Sophie is part of the first cohort of patients to receive NK101 in Cancun, Mexico (page 35) in an effort to eliminate what is left of the tumor.

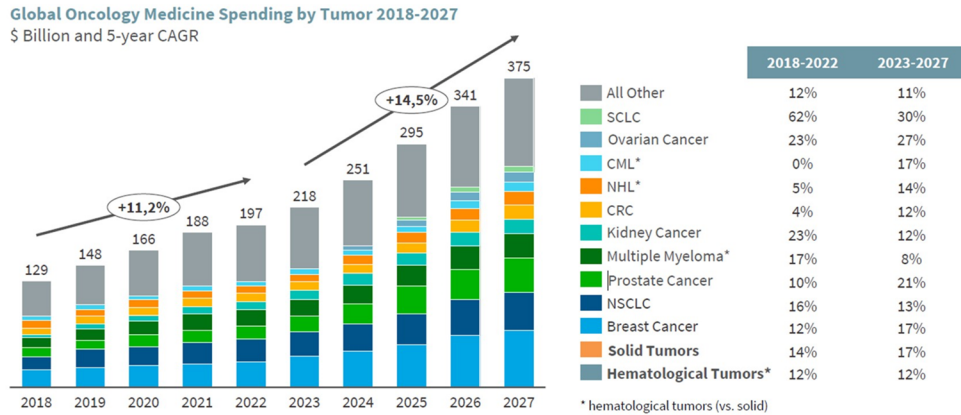
CANCER OVERVIEW

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths, derived from 19.3 million new cases (Source: World Health Organization). In the U.S., cancer is the second leading cause of death, with over 1.9 million new cancer cases expected in 2023—equivalent to more than 5,200 new cases each day—resulting in approximately 610,000 deaths. Cancer also represents a significant economic burden. Cancer-related medical costs are expected to reach almost \$209 billion by 2020, with costs likely to rise as the population ages and its prevalence increases. Costs are also expected to increase as new, and often more costly treatments are adopted as standards of care (Source: American Cancer Society's Cancer Facts and Figures 2023).

Oncology Market Overview

The oncology market is one of the largest pharmaceutical markets and, with the introduction of novel and improved treatments, it is expected to continue to expand. Globally, the oncology market is forecast to reach \$375 billion in 2027, up from \$196 billion in 2022, with seven of the global top 10 forms of cancer exhibiting double digit spending growth during the same period (Figure 7 [page 20]). The continued development and launch of innovative therapeutic options are one of the key drivers fueling the growth, with emerging biopharma companies expected to lead innovation, accounting for over 71% of product candidates in the oncology pipeline (Source: IQVIA's *Global Oncology Trends 2023, Outlook to 2027, 2023*).

Figure 7
 GLOBAL ONCOLOGY SPENDING



Source: IQVIA Global Oncology Trends 2023, Outlook to 2027, 2023.

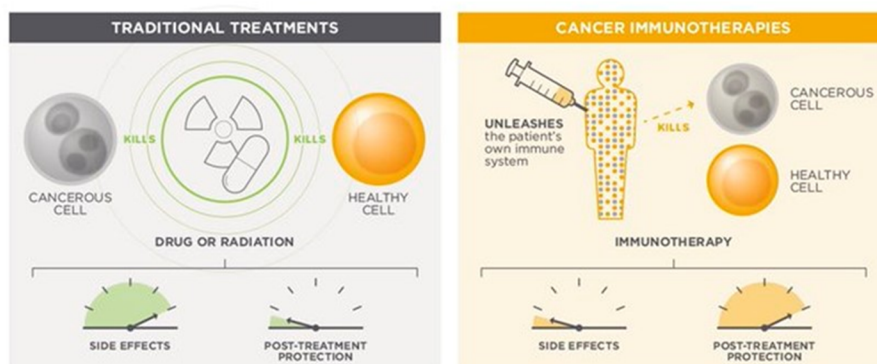
Cancer Immunotherapy Background

For decades, the main treatment options for oncology patients following surgery have been chemotherapy and radiotherapy. However, these therapies are associated with severe toxicities, which can reduce physical strength and impair immune response, which can lead to recurrence as well as metastasis of remaining tumor cells. Furthermore, the development of resistance to chemotherapy and/or radiotherapy is also associated with a high incidence of cancer recurrence.

To counteract the severe toxicities and stagnant survival rates normally associated with current cancer treatments, researchers are developing new cancer therapies with improved efficacies and more favorable safety profiles that selectively attack only the cancer cells without harming surrounding healthy cells. One prominent method, called immunotherapy, utilizes the body's own immune system to fight the disease. Immunotherapy, or biological therapy, is a type of cancer treatment that boosts the body's natural defenses to fight, helping the patient's body fight cancer by eliciting the following effects: (1) stop or slow the growth of cancer cells; (2) stop cancer from spreading to other parts of the body; and (3) help the immune system work better at destroying cancer cells.

Immunotherapies also provide significant advantages over conventional cancer treatments, such as chemotherapy or radiation. Since immunotherapy can train the immune system to recognize and remember cancer cells, it may result in longer-lasting remissions. Clinical studies on long-term overall survival have shown that the beneficial responses to cancer immunotherapy treatment are maintained even after treatment is completed. Furthermore, since cancer immunotherapy is focused on the immune system and may be more targeted than conventional cancer treatments, it normally presents a better safety profile when it comes to side effects. Conventional chemical or radiological cancer therapy normally affects both the cancerous cells as well as healthy tissues, which results in common side effects, such as hair loss and nausea, but also can cause immunosuppression, weakening the body's immune system and affecting the body's post-treatment protection against infections and recurrent cancers, as seen in Figure 8 (page 21) (Source: Cancer Research Institute).

Figure 8
IMMUNOTHERAPY VS. CHEMOTHERAPY

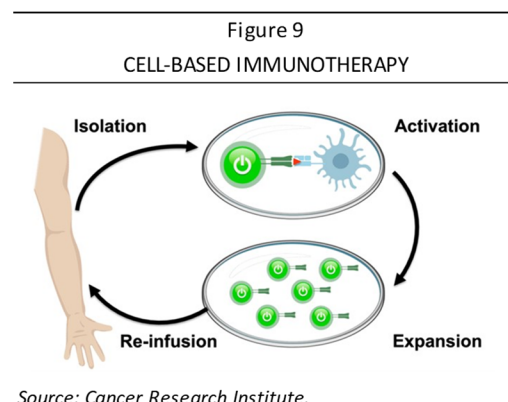


Source: Adaptive Biotechnologies.

NATURAL KILLER (NK) CELL IMMUNOTHERAPY

One promising immunotherapy approach is cell-based immunotherapy (also known as adoptive cell therapy), which uses an immune system’s cell as therapeutic agent. For this purpose, the selected immune cells are first removed from the body, then activated or modified to enhance their cancer-fighting capabilities, expanded, and finally re-infused into the patient (Figure 9).

Interest in adoptive cell therapy has significantly increased due to the early clinical successes of autologous chimeric antigen receptor T lymphocyte therapy (CAR-T)—where T-cells are extracted from the patient and enhanced before being re-infused—the first cell therapy to enter commercialization. CAR-T therapy has led to incredible improvements in patients with certain types of aggressive malignancies. Since 2017, the FDA has approved six CAR-T cell therapies. All are approved for the treatment of blood cancers, including lymphomas, forms of leukemia, and most recently, multiple myeloma.



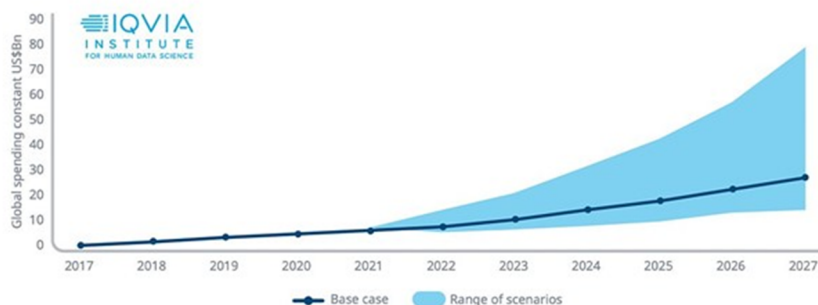
Source: Cancer Research Institute.

However, despite early successes, CAR-T cell therapy has significant limitations. The complex manufacturing process increases costs and takes weeks to generate, thus representing an obstacle for patients who are in critical need of treatment. Furthermore, the requirement for the patient’s own cells as the source material restricts eligibility, as patients are often heavily pretreated. CAR-T cells are also associated with significant toxicities, including cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, and prolonged cytopenias. In addition, despite the successes of engineered T-cell immunotherapies, the clinical benefit has been limited to a fraction of patients and a few indications, thus highlighting the need for a new strategic approach (Source: *Nature Reviews Cancer*, Vol. 22: 557–575, 2022).

To overcome these issues, natural killer (NK) cells are being explored as an alternative cell source for allogeneic cell therapies. NK cells, part of the innate immune system, have an inherent ability to recognize and eliminate cancer cells, while avoiding toxic responses associated with CAR-T cell therapy. These various attributes provide NK cells with unique advantages for allogeneic therapeutic applications. With the accelerated development of innovative strategies and the emergence of next-generation technologies that allow for deeper biological investigations, various NK cell products can be designed for cancer treatment (Source: *Blood*, Vol. 141(8):856-868, 2023).

Global spending on cell, gene, and RNA therapeutics was estimated at \$8 billion in 2021 and is expected to rise to \$27 billion by 2027. As shown in Figure 10, these estimates have the potential for significantly higher or lower scenarios, as it depends on the introduction and acceptance of the novel and experimental technologies, with the high scenario of more than \$70 billion (Source: IQVIA’s *The Global Use of Medicines 2023, Outlook to 2027, 2023*).

Figure 10
 CELL THERAPEUTICS MARKET

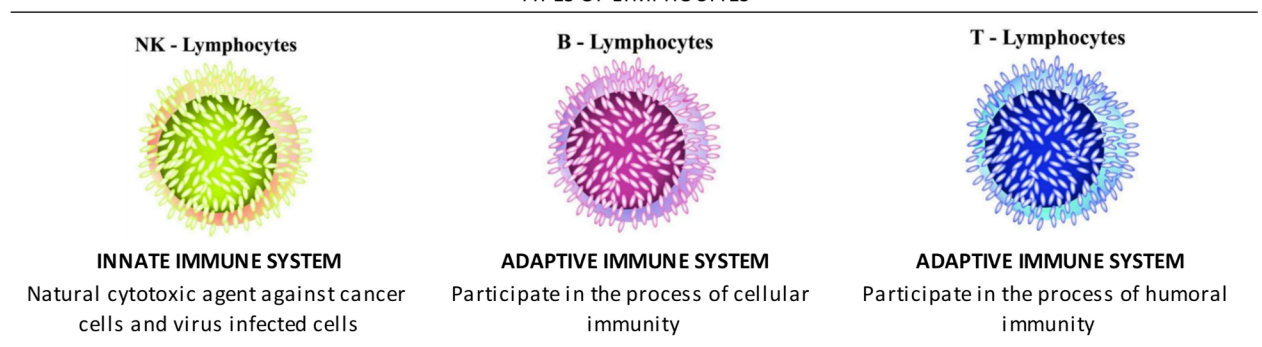


Source: IQVIA’s *Global Use of Medicines, 2023*

What are Natural Killer (NK) Cells?

Natural Killer (NK) cells are cytotoxic cells considered to be key components of the innate immune system. NK cells function as the body’s natural defense mechanism, killing virally infected cells and detecting and controlling early signs of cancer in the initial stages, preventing their spread. NK cells belong to a specific group of white blood cells called **lymphocytes**, which also includes B-cells and T-cells, as seen in Figure 11. NK cells, comprising about 5% to 15% of the lymphocytes circulating in the blood, have a short lifespan of about two weeks.

Figure 11
 TYPES OF LYMPHOCYTES



Source: *Narayana Health*.

As cells of the innate immune system, NK cells respond quickly to a wide variety of pathological challenges. This ability comes from the fact that NK cells are called “natural” killers because they can destroy potential threats without prior exposure to a particular pathogen. Other lymphocytes of the adaptive immune system, such as T- and B-cells, need previous exposure to a pathogen before they can destroy it.

NK Cells Role Against Cancer

NK cells are known to be critical in the fight against cancer. While T-cells have been the primary focus of cancer immunotherapy, it is recognized that in the prevention of metastases through the elimination of circulating cancer stem cells with high metastatic potential, NK cells are the main immune effector cells. This is due to their unique ability to identify and spontaneously kill poorly differentiated cancer stem and stem-like cells that do not express MHC class I on their surface without prior sensitization. Given the propensity of solid tumors to down-regulate the surface expression of MHC class I, this unique function of NK cells is critical in those circumstances where cytotoxic T-cells, which require MHC class I for tumor recognition and elimination, are incapable of mounting an immune response.

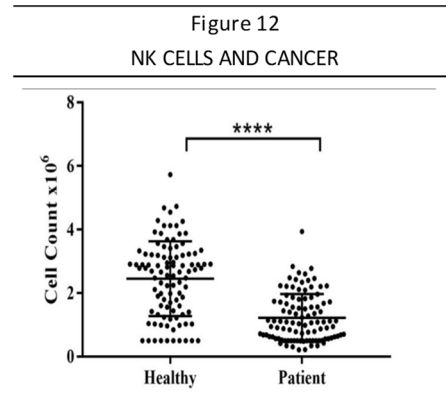
While an NK cell's primary job is killing infected and cancerous cells, these immune cells are also capable of releasing cytokines and chemokines, including gamma interferon (IFN- γ) and tumor necrosis factor alpha (TNF α), that promote an inflammatory immune response and play an important role in regulating T-cells and other adaptive immune cells to mount an immune response and attack harmful cells and pathogens.

In addition, it has been recently proposed that NK cells also exhibit a crucial role in the control of metastasis by eliminating circulating cancer cells with stem-like cell characteristics. Cancer stem cells (CSCs) are a subpopulation of tumor cells sharing similar characteristics as normal stem or progenitor cells, such as self-renewal ability and multi-lineage differentiation. Their presence is recognized as a crucial factor contributing to tumor progression and metastasis. Conventional cancer treatments target the bulk of the tumor but are unable to target CSCs due to their highly resistant nature, leading to tumor recurrence and metastasis. Considering these findings, eradicating or differentiating (and thus eliminating their self-renewal ability) the CSC subpopulation is a potential strategy for cancer treatment (Source: *Molecular Cancer*, Vol. 22 (171), 2023).

NK cells play a dual role in the elimination of CSCs. NK cells have been shown to selectively kill CSCs as well as eliminate circulating cancer cells with stem-like cell characteristics, a crucial role in the control of metastasis. In addition, NK's secretion of functional IFN- γ can induce CSCs differentiation, resulting in CSCs eradication and decreasing the possibility of recurrence and metastasis (Source: *Communications Biology*, Vol. 5 (436), 2022).

Tumor Microenvironment (TME) and NK Cells

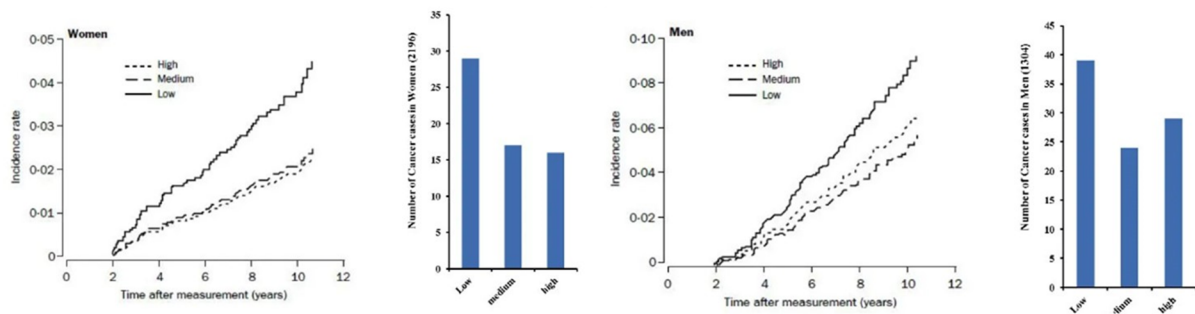
NK cells provide the first line of defense against carcinogenesis and are closely related to cancer development. However, the tumor microenvironment (TME) has been shown to suppress both the number and the function of NK cells. Several clinical studies have confirmed the close relationship between NK cells and cancer development. The number of NK cells in the cancer tissues has been shown to be lower than normal, as seen in Figure 12. This finding is significant, as individuals with lower NK cell cytotoxicity are more susceptible to cancer. In addition, individuals with higher NK cell numbers and cytotoxicity have a reduced risk of cancer and a more favorable prognosis. Furthermore, the TME not only affects the number of NK cells, but also inhibits NK cell function, diminishing IFN- γ secretion and function, reducing cytotoxicity against cancer cells, and adversely influencing other anti-cancer processes (Source: *Cancers (Basel)*, Vol. 13(16): 4129, 2021).



Source: *Nature Research's Scientific Reports*.

In one study, researchers measured cytotoxic activity in 3,625 subjects between 1986 and 1990, with an 11-year follow up. Results indicate that medium and high cytotoxic activity of peripheral-blood lymphocytes is associated with reduced cancer risk in both men and women, whereas low activity is associated with increased cancer risk, as seen in Figure 13 (page 24) (Source: *The Lancet*, Vol. 356 (9244): 1795-1799, 2000).

Figure 13
 NATURAL KILLER CELLS AND CANCER RELATIONSHIP



Source: NKore BioTherapeutics, LLC.

Overall, the TME have been found to have the following negative effects on NK cell function:

- Decreased number of NK cells;
- Decreased cytotoxicity against cancer stem cells;
- Decreased secretion of IFN- γ and TNF- α ;
- Decreased IFN- γ function, lacking the ability to differentiate tumors resulting in greater metastatic potential; and
- Decreased ability to expand (i.e., not possible to supercharge/repair defective NK cells).

NK cells are essential in resisting carcinogenesis. As the development and progression of cancer are correlated with the dysfunction of NK cells, the ability to enhance the function of NK cells to resist the negative effects of the TME through novel cell immunotherapy strategies could be key for the development of more effective treatment options for cancer patients.

NK Cell-based Immunotherapy

NK cell-based immunotherapy is a promising alternative platform for cellular immunotherapy, as scientific discoveries related to NK cells and their essential role against cancer are creating new pathways for the development of more effective antitumor treatment strategies.

While NK cells can recognize and attack cancer cells, multiple immunosuppressive factors in the TME negatively affect the number and the immune function of NK cells, interfering with its anticancer activities. Immunotherapy strategies focusing on recovering the effector function of NK cells are crucial to address deficiencies created by the TME. Different techniques for the extraction of healthy NK cells, in vitro activation and enhancement, and expansion have been evaluated to enhance NK cells' anti-tumor activity and give them the ability to overcome the toxic TME environment (Source: *Cancers (Basel)*, Vol. 13(16): 4129, 2021).

These approaches have been translated into clinical applications, with NK cell-directed immunotherapies currently in several preclinical and clinical studies for treatment of hematological malignancies and solid tumors. These studies have resulted in promising therapeutic effects and safety, with results indicating preclinical anti-malignant activity both in hematological cancers and solid tumors, including leukemia, lymphoma, myeloma, ovarian cancer, and glioblastoma (Source: *Journal of Translational Medicine*, Vol. 20 (240), 2022).

Compared to other immunotherapies, NK cell therapy, specifically allogenic NK cell therapy (which NKore is utilizing), has significant advantages in terms of efficacy, ease and speed of manufacturing, and safety:

- NK cells do not need to be genetically engineered or modified to recognize cancer cells. This results in a simplification of the complex, costly, and lengthy manufacturing process normally associated with other forms of immunotherapy. As such, NK cell therapy provides a cost and time advantage over other immunotherapies.
- In allogeneic NK cell therapy, NK cells are harvested from healthy individuals. On the other hand, for autologous NK cells therapy, the cells are often obtained from heavily pretreated or diseased patients where the active cancer results in limited expansion efficiency and cytotoxicity of the harvested NK cells, limiting their therapeutic efficacy.
- NK cell therapy provides a better safety profile compared to other forms of cancer treatment, such as chemotherapy, radiation, and even other immunotherapies. Both standard treatments as well as other immunotherapies are associated with severe toxicities, which can reduce physical strength and impair immune response. For example, CAR-T cell therapy is sometimes associated with fatal toxicity side effects, such as cytokine release syndrome (Sources: Siteman Cancer Center, and *Cancers (Basel)*, Vol. 13(16): 4129, 2021).

NK101—Supercharged NK Cells (sNK)

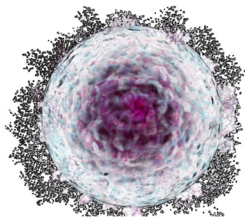
NKore strives to position itself at the forefront of the detection, prevention, and treatment of cancer using its innovative cellular-based immunotherapies with supercharged NK cells to significantly improve patient outcomes while lowering the overall cost of care.

NKore’s NK cell immunotherapy technology platform is based on a proprietary method of activating and expanding donor NK cells to significantly enhance their cytotoxic effect and function against cancer cells. NK cells have two main functions in preventing cancer: (1) to target and spontaneously kill cancer stem and stem-like cells and poorly differentiated tumors (or other abnormal cells) in the body through cell mediated cytotoxicity; and (2) to secrete gamma interferon (IFN- γ) and tumor necrosis factor alpha (TNF- α) to induce the differentiation of those cancer stem cells that avoid cell death.

However, the tumor microenvironment (TME) has been shown to suppress both the number and the function of NK cells, reducing cytotoxicity against cancer cells, diminishing IFN- γ secretion, and adversely influencing other anti-cancer processes (Source: Cancers (Basel), Vol. 13 (16): 4129, 2021).

To overcome this TME driven impairment, Dr. Anahid Jewett (the Company’s co-founder and Chief Scientific Advisor) developed a method to activate NK cells obtained from healthy donors (allogeneic cells) to create NK101—supercharged NK cells (sNK)—for clinical use as a cellular-based immunotherapy. The activation method used to produce NK101, explained on page 27, has been specifically developed to make the allogeneic NK cells more potent and more robust to enable the cells to withstand the suppressive TME. The proprietary activation method makes the NK101 cells significantly more potent by enhancing the cytotoxic function, while increasing the secretion of functional IFN- γ to induce the differentiation of the cancer stem cells, thus reducing the likelihood of tumor regeneration and metastasis. In addition to being more potent, NKore’s activation method also makes the activated NK cells more robust to allow them to better withstand the suppressive TME (summarized in Figure 14).

Figure 14
NK101 - SUPERCHARGED NK CELLS



Proprietary activation method based on Dr. Jewett's research.

Activation method produce NK101 cells (supercharged NK cells):

- More potent NK cells
- Enhanced the cytotoxic function
- Increase secretion of IFN- γ to induce differentiation of CSCs
- More robust to better withstand tumor microenvironment (TME)

Source: NKore BioTherapeutics, LLC.

The proprietary activation method was developed by Dr. Anahid Jewett, based on her 30-plus years spent researching NK cell function and disease progression. Her research has yielded significant discoveries and findings, including:

- Defined the NK cell maturation cycles;
- Identified the mechanism of action of the NK cells in attacking tumor cells;
- Identified the effect of the tumor microenvironment (TME) on NK cell function; and
- Developed NKore’s novel method to activate and expand the NK cells to produce the sNK cells.

NK101

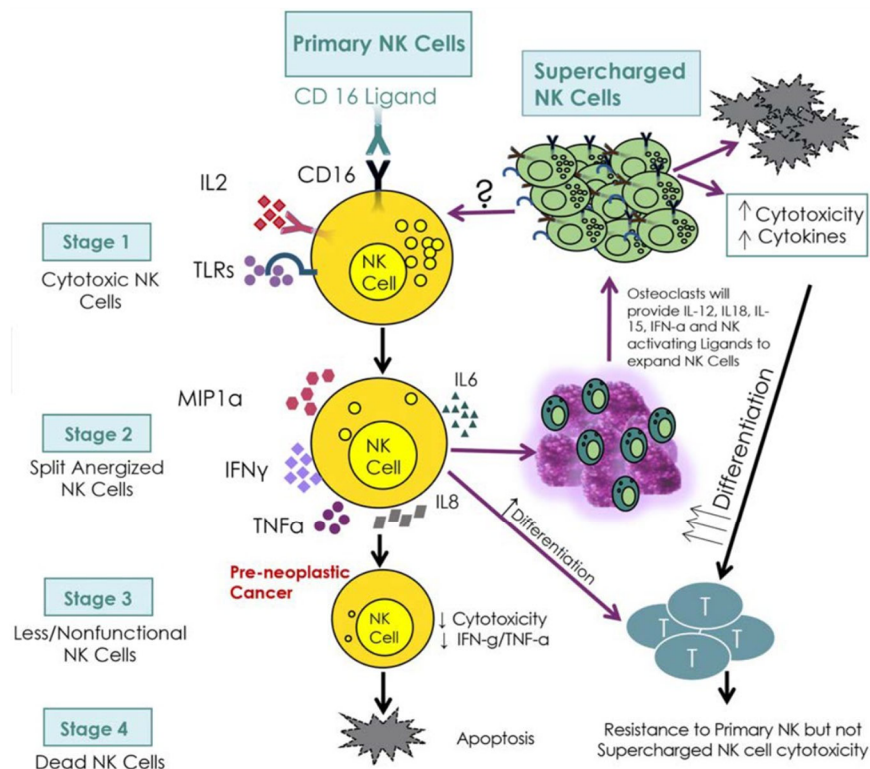
Working with Dr. Jewett, NKore has developed NK101, a cellular-based immunotherapy that in preclinical studies has proven effective in treating both solid tumors and hematologic malignancies, including glioblastoma, pancreatic, oral, lung, ovarian, breast, liver, lymphoma, and leukemia. These studies have demonstrated NK101’s potential to not only stop or reverse disease progression, but to also restore immune function in some of the animals.

NK101 Production Process

The proprietary NK101 production incorporates the collection of allogeneic NK cells from healthy donors, then is formulated by expanding and activating the NK cells in vitro using the proprietary method developed by Dr. Jewett. NK101 is formulated to be administered to patients via infusion therapy (IV drip) under the supervision of a treating physician.

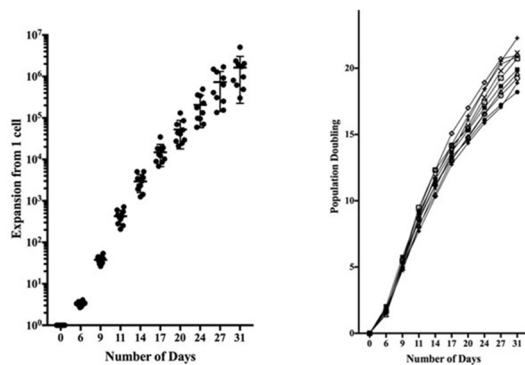
NKore’s expansion and activation of the NK cells is based on a proprietary strategy to produce large numbers of sNK cells using activating feeder cells. Immunotherapy with NK cells has been limited, at least in part, due to an inability to obtain enough highly functional NK cells. Several in vitro NK expansion techniques have been developed to allow for a higher therapeutic cell dose, including the use of dendritic cells and monocytes as feeder cells. NKore uses a different novel expansion process using other feeder cells, yielding NK cells with levels and functionality that the Company believes is significantly superior to those established by other methodologies (Figure 15).

Figure 15
 SUPERCHARGED NK CELL ACTIVATION METHOD



Source: NKore BioTherapeutics, LLC.

Figure 16
 NK CELL EXPANSION POTENTIAL



Each substance used in the expansion/activation process plays a specific role in the creation of the sNK cells to enhance cytotoxicity and produce optimal secretion of both pro-inflammatory and anti-inflammatory cytokines in NK cells to induce the differentiation of those CSCs that avoid cell death.

As seen in Figure 16, this activation method yielded NK cell expansion of 21,000- to 132,000-fold at day 20 and 300,000- to 5,100,000- fold on day 31, with 17–21 population doublings within 4 weeks (Source: *Frontiers of Immunology*, Vol. 8 (297), 2017).

Supercharged NK (sNK) Cells’ Capabilities

Source: *Frontiers in Immunology*.

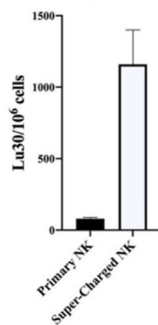
The Company’s activation method results in Supercharged NK (sNK) cells, named for the superior cytotoxic activity, higher IFN- γ secretion, and longer survival when compared to other expansion methodologies (Source: *Oncoimmunology*, Vol.7 (5): e1426518, 2018). When NK cells are activated and expanded using the proprietary method, they show the following benefits:

- Significant expansion potential;
- Significant cytotoxic function enhancement;
- Secretion of more IFN- γ and TNF- α to induce differentiation and reduce the metastatic potential of the tumor cells; and
- More robust NK cells that better withstand the suppressive tumor microenvironment.

Cytotoxicity

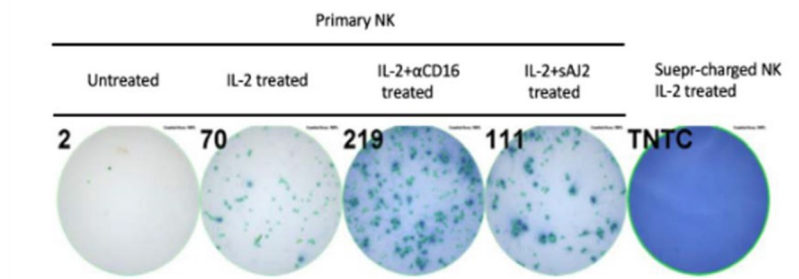
The novel activation method enhances the cytotoxic function of the NK cells, targeting and killing not only the poorly differentiated cancer stem and stem-like cells, but also the differentiated tumor cells that regular NK cells are unable to target (Figure 17). In addition, sNK can better withstand the suppressive tumor microenvironment.

Figure 17
 sNK CYTOTOXICITY



Source: NKore BioTherapeutics, LLC.

Figure 18
 IFN-GAMMA EXPRESSION



Source: NKore BioTherapeutics, LLC.

Differentiation

Cancer stem cells (CSCs) self-renewal ability and multi-lineage differentiation are recognized as a crucial factor contributing to tumor progression and metastasis. Differentiating (and thus eliminating their self-renewal ability) the CSC subpopulation is a potential strategy for cancer treatment (Source: *Molecular Cancer*, Vol. 22 (171), 2023).

NKore's proprietary activation method yield sNK cells that increases the secretion of functional IFN- γ (Figure 18 [page 28]) and TNF- α , inducing the differentiation of aggressive undifferentiated cancer stem and stem-like cells in the tumor microenvironment, making them more susceptible to other forms of cancer treatment, including chemotherapy, radiation therapy, and multiple forms of immunotherapy.

PRE-CLINICAL AND CLINICAL RESULTS

In preclinical studies, sNK cells have proven highly effective in targeting and lysing aggressive solid tumor cells and hematologic cancer cells. NK101 immunotherapy has been evaluated in preclinical models of pancreatic tumor cells, glioblastoma, ovarian cancer, as well as melanoma, lung cancer, breast cancer, and hematologic malignancies. The common denominator for many of these diseases is a less than 5% survival rate when diagnosed at later stages.

Based on these preclinical studies, NKore believes that NK101-based immunotherapy can slow or reverse the progression of disease and reduce the metastatic potential of the remaining tumor cells, improving the prognosis for the patient. The Company believes that NK101 immunotherapy could be used as a monotherapy in early-stage cancers, and as a combination therapy for other mid- and late-stage cancers, based on its increased cytotoxic activity and its potential ability to eliminate cancers stem and stem like cells, reduce the likelihood of metastasis, and restore immune function to make the other therapies more potent. Figure 19 lists an overview of the potential benefits of NK101-based immunotherapy.

Figure 19
 NK101 CELL THERAPY BENEFITS

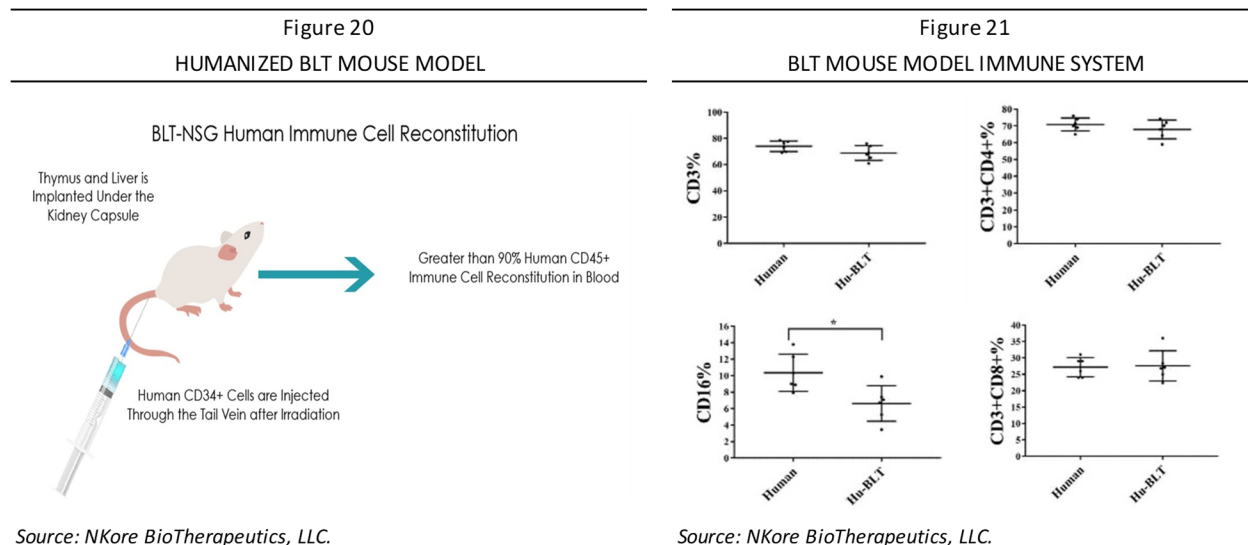
- Unique safety profile in preclinical animal models:
 - No evidence of cytokine release syndrome (CRS)
 - No GvHD
 - No neurological symptoms or evidence of toxicity
- Ability to target and spontaneously kill both poorly differentiated and well differentiated tumor cells.
- In preclinical models, acts as a catalyst to mobilize, and potentially restore, immune function (own pNK, T-cells, Dendritic cells) to correct the cellular conditions that led to disease progression.
- Potential to enhance the efficacy of other cancer treatments (chemo, radiation, checkpoint inhibitors).
- In preclinical models, effective in the treatment of solid tumors and hematologic malignancies, including pancreatic cancer, glioblastoma, oral, lung, breast, liver, ovarian, leukemia and Non-Hodgkin's lymphoma.

Source: NKore BioTherapeutics, LLC.

Humanized Mouse Model

A considerable portion of the NK101 preclinical studies were conducted by Dr. Jewett using humanized bone marrow-liver-thymus (BLT) mice, a mouse model developed to more closely replicate the human immune system. The BLT mouse model provides a powerful tool to study human immunology and immunotherapies at a cellular level. Overall, Dr. Jewett evaluated sNK cells in preclinical models that included over 350 BLT mice. Given the similarities to the human immune system, NKore believes that the use of this mouse model in the preclinical studies should increase the probability that the preclinical results can be translated into patients in human trials.

BLT humanized mice are generated by surgically implanting fragments of human fetal liver and thymus tissue under the kidney capsule of immunodeficient mice, followed by tail vein IV injection of human derived CD34+ hematopoietic stem cells (HSC) (Figure 20). The process supports the long-term engraftment of the HSC in the mouse bone marrow, leading to a systemic reconstitution of a nearly complete human immune system, including multilineage human adaptive and innate immune cells consisting of T-cells, B-cells, NK cells, dendritic cells, and macrophages (Source: *Stem Cells and Development*, Vol. 25 (24), 2016).



The resulting humanized mice display human T-cell reconstitution, maturation, and selection, with over 90% human cell reconstitution in eight weeks. As seen in Figure 21, the expression of human CD3, CD4, CD8, and CD16 cells in peripheral blood of humanized-BLT mice resembled that of human peripheral blood (Source: *Oncoimmunology*, Vol.7 (5): e1426518, 2018). Of note, while CD3, CD4, and CD8 need to be like healthy humans, CD16 is lower in humans with cancer, hence creating the best possible in-vivo model.

Preclinical Research: Representative Summary of Studies

The Company's technology platform was developed by Dr. Anahid Jewett, based on her 30-plus years spent researching NK cell function. Dr. Jewett's NK cell function research has yielded significant discoveries and findings about the NK cells' functions in general and their role in cancer. The findings—published in *Current Opinion in Immunology* (Vol. 51:170–180, 2018)—include the following, among others:

- NK cells play a significant role in differentiation of cancer stem cells;
- Osteoclasts, dendritic cells, and monocytes are major inducers of NK cell activation;
- Secreted TNF-a and IFN-γ from NK cells mediate differentiation of cancer stem cells; and
- NK cells target and kill cancer stem cells but not their differentiated counterparts.

Specifically, Dr. Jewett's research focused on the role of NK cells and their use as potential cancer treatment options. In this regard, Dr. Jewett identified the effect of the tumor microenvironment on NK cell function, the mechanism of action of the NK cells in attacking tumor cells and cancer stem cells, and developed NKore's novel method to activate the NK cells to produce the sNK (NK101).

In addition, Dr. Jewett and NKore have conducted preclinical studies to assess the potential use of NK101 sNK cells in specific cancer types, where sNK cells have proven highly effective in targeting and lysing aggressive solid tumor cells and hematologic cancer cells. The sNK cells have been evaluated in preclinical models of pancreatic tumor cells, glioblastoma, ovarian cancer, as well as melanoma, lung cancer, breast cancer, and hematologic malignancies. A list of these studies is provided in Figure 22, followed by an overview of selected studies.

Figure 22
 SELECTED PRE-CLINICAL STUDIES

Disease State Studied	# Animals (n)
Pancreatic Cancer in Hu- BLT Mice	NSG mice= 9 and Hu-BLT mice=129
Oral Tumors in Hu- BLT Mice	Hu-BLT mice= 95
Supercharged NK Cell Expansion Preferentially Select and Expand CD8+ T Cells	Hu-BLT mice= 27
Pancreatic Cancer in Obese Mice	KRAS WT Mice = 19
Suppression of Gingival NK Cells in Pancreatic Cancer in KC & BLT Mice	KC Mice = 8 & BLT = 15
Glioblastoma in Tumorspheres	Tumorspheres = 9
Differences in NK Cell Expansion & Function b/t Healthy and Cancer Patients	Hu-BLT mice= 8
NK Cell Cytotoxicity & IFN-γ Secretion after interaction w/ Monocytes	Wild type mice= 9 and Knock out mice= 9
Defects in NK Cells in Cancer Patients	Hu-BLT mice= 3
Breast Cancer	NUDE Mice - 6 animals per group, 12 in total
Leukemia	SCID Mice= 25
Tumor Necrosis in Vitro	In Vitro Analysis
OVCAR-8 Ovarian Cancer	In Vitro Analysis

Source: NKore BioTherapeutics, LLC.

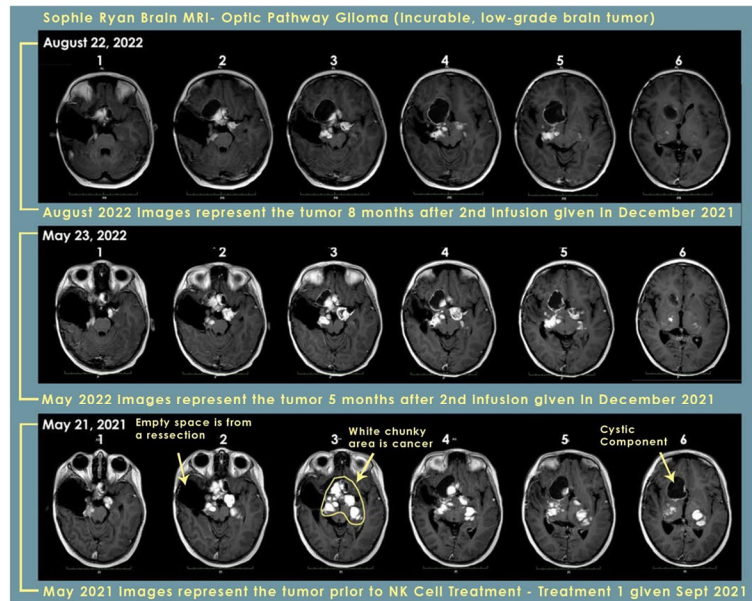
Proof of Concept of Activated NK Cells Effectiveness.

Dr. Jewett first met Ms. Tracy Ryan (NKore’s co-founders) due to Ms. Ryan’s daughter’s (Sophie) incurable Grade 1 Optic Pathway Glioma brain tumor, which was diagnosed when she was 8 months old. Sophie failed seven different chemotherapy and clinical trial protocols, had 11 surgeries including five 5 brain surgeries, and her tumor had not shrunk in the five-year period prior to her treatment with the IL-2 activated NK cells.

Dr. Jewett determined that Sophie had no functioning NK cells in her brain, even though she had excellent NK cell function from the neck down. Through an existing collaboration, Sophie’s clinical team developed a protocol to use direct to donor NK cells from Sophie’s father, activated with IL-2, which are different than NKore’s NK101 sNK cell immunotherapy. In Dr. Jewett’s preclinical research, the use of IL-2 activated NK cells has been shown to be much less effective than the use of sNK cells, but the IL-2 activated cells were used in this case due to the lack of FDA approval required to administer the sNK cells in the U.S. Sophie received this treatment prior to the commencement of manufacturing in Cancun and, therefore, NK101 was not available as a therapeutic option.

Two “IL-2 activated” NK cell therapy infusions were formulated using Sophie’s father’s NK cells and administered by IV drip in September 2021 and December 2021. At 2 1/2 months following the second infusion, the tumor began to shrink. Sophie’s tumor continued to shrink for 16 months post-infusion, with clinical evidence of presence of functional NK cells at 16 months (Figure 23 [page 32]). While Sophie had substantially less evidence of disease left in her brain following her treatment with the IL-2 activated NK cells, she was the second patient to receive NK101 in Cancun in an effort to kill the remaining tumor cells and eliminate any remaining disease. The treatment is described on pages 35-46.

Figure 23
OPTIC PATHWAY GLIOMA - ACTIVATED NK CELLS



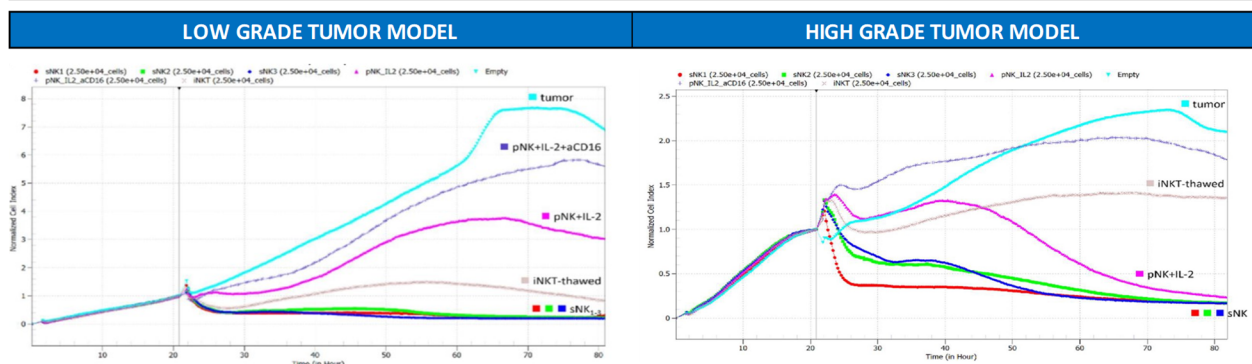
Source: Cannabis Science and Technology.

Overall, the effective use of IL-2 activated NK cells corroborates the potential for the use of NK101 and other non-engineered NK cells as an immunotherapy option for cancer. The use of IL-2 activated NK cells resulted in: (1) over 85% reduction in tumor size with evidence of continuing tumor cell death; (2) clinical improvement in muscle coordination, vision, and visual acuity; and (3) significant improvement in immune function in blood and brain fluid.

Comparison of Cytotoxicity of IL-2 Activated NK Cells to sNK Cells.

Despite the effective use of IL-2 activated NK cells in the previous case, preclinical trials conducted by Dr. Jewett demonstrate that sNK cells have superior cytotoxic activity when compared to IL-2 activated NK cells in both low-grade (differentiated) and a high-grade (poorly differentiated) oral squamous cancer cells. In vitro analyses were performed to compare the cytotoxic activity of sNK versus IL-2 activated NK cells. In the low-grade model, only the sNK cells killed all the tumor cells, with three different samples of sNK cells killing all the tumor cells almost immediately (Figure 24, left side). In the high-grade model, the sNK cells killed all the stem-like tumor cells while the IL-2 activated cells killed most, but not all (Figure 24, right side).

Figure 24
sNK CELLS vs. IL-2 ACTIVATED NK CELLS



Source: NKore BioTherapeutics, LLC.

*Humanized mouse Trials on Pancreatic Cancer
 (Source: Cancers Vol. 12 (63), 2020)*

Dr. Jewett also assessed the effect of sNK cells in implanted tumors in the pancreas of humanized-BLT (hu-BLT) mice. Following tumor implantation, mice received injections of sNK cells via the tail vein after one to two weeks and disease progression was monitored. The mice were euthanized after 6-7 weeks.

Three different hu-BLT mice groups were studied: (1) mice surgically implanted with stem-like/undifferentiated pancreatic tumors in the absence of sNK cells; (2) mice surgically implanted with stem-like/undifferentiated pancreatic tumors and then injected with sNK cells; and (3) mice surgically implanted with pancreatic tumors that had been differentiated by the sNK cell supernatants prior to implantation.

In the first group, stem-like/undifferentiated pancreatic tumors grew rapidly (within 4 weeks), forming large tumors, and metastasized to the liver, causing significant morbidity and mortality in the mice. In the second group, a single injection of sNK cells was found to inhibit tumor growth and increase immune cells in the pancreas of the hu-BLT mice. In this group, following injection of sNK cells, subjects formed much smaller and proliferated less. In the last group, the implanted differentiated tumors were not able to grow or grew smaller tumors and were unable to metastasize. In addition, they were also found to be more susceptible to chemotherapeutic drugs, whereas poorly differentiated tumors were resistant. Figure 25 shows the difference in tumor growth for the three groups.

Figure 25
 sNK IN PANCREATIC CANCER MODEL



Source: Cancers, 2020.

These results not only indicate the ability of sNK cells to positively affect tumor growth, but also the importance of the elimination of undifferentiated stem-cell like tumor cells in the long-term prognosis of cancer patients. Results show that sNK cells drive selection and differentiation of pancreatic poorly differentiated tumors, resulting in inhibition of their aggressiveness and metastatic potential, and increased susceptibility to chemotherapy. These in vivo results complement previous in vitro findings for the role of NK cells in the selection and differentiation of poorly differentiated tumors of glioblastoma, pancreatic, oral, lung, breast, and melanomas.

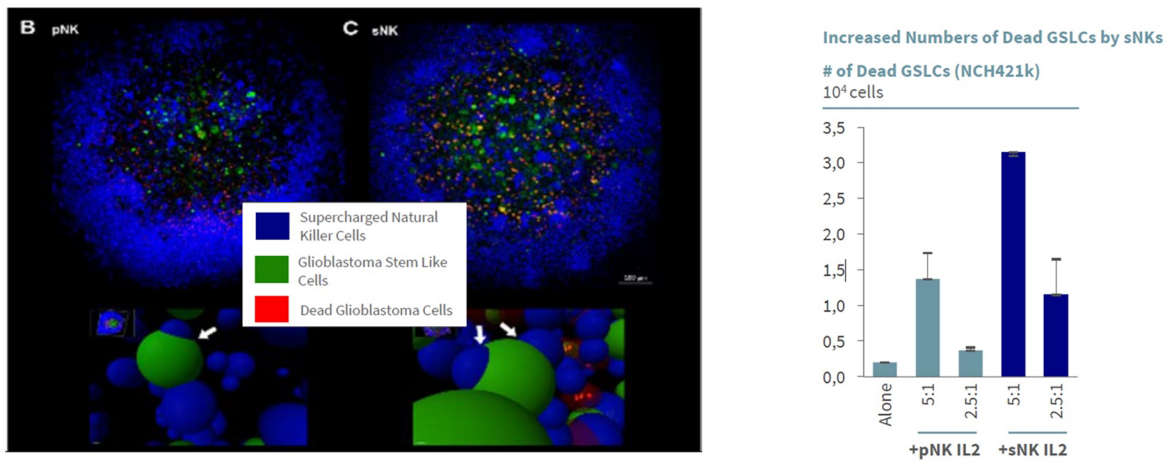
*Effect of sNKs on Glioblastoma Stem-Like Cells (GSLCs)
 (Source: Communications Biology, Vol5:436, 2022)*

Glioblastomas (GMB) remain among the most aggressive and lethal malignancies of the brain, with little or no progress in the standard treatment for nearly 20 years. Only 5% of the patients survive 5 years or more and only half of the patients are still alive at 15 months after diagnosis. NK cell-based therapy is a promising immunotherapeutic strategy in the treatment of glioblastomas, since these cells can select and lyse therapy-resistant glioblastoma stem-like cells (GSLCs), which are resistant to standard therapy due to efficient DNA repair mechanisms and multidrug resistance causing regrowth of GBM tumors.

In this study, researchers investigated the therapeutic potential of allogeneic sNK cells in GBM tumors by comparing primary NK (pNK) cells to sNK cells in a GSLC tumorsphere model. The NK cells showed the ability to penetrate the GBM tumors and directly interact with GSLCs. However, it is known that primary NK cell function is impaired in the peripheral blood of GBM patients in comparison to healthy donors. In an effort to counteract this effect, researchers also analyzed primary NK cell and sNK cell mediated cytotoxicity and secretion of pro-inflammatory cytokines in 2D and 3D in vitro GBM models.

Results indicated sNK cells were shown to eliminate GSLCs in 2D and 3D cellular models more efficiently than the primary NK cells. For example, although both primary and sNK cells penetrated the GSLC tumorspheres, decreasing the numbers of GSLCs and increasing the number of dead cells, sNK cells exhibited better cytotoxic activity and much higher killing than primary NK cells, as seen in Figure 26. Finally, in addition to improved cytotoxicity, sNK cells secreted pro-inflammatory IFN- γ and IL-6 and increased sensitivity of GSLCs to chemotherapeutic drugs.

Figure 26
 sNK IN GLIOBLASTOMA



(Source: Communications Biology, 2022).

Immunotherapy with allogeneic sNK cells appears a promising therapeutic approach in the treatment of GBM by selectively killing the malignant cancer stem-like cell population, potentially reversing the immunosuppression normally found in patients, and increasing GSLC's susceptibility to chemotherapy.

Single Infusion of Allogeneic sNK Cells

Prior to NKore's incorporation, Dr. Jewett entered a clinical trial collaboration in China for the treatment of a patient with non-Hodgkin's lymphoma who presented with a lesion telescoping from the roof of his mouth towards the brain. The patient received a single infusion of roughly 350 million sNK cells, activated following the previously described proprietary method. fourteen-days post-infusion, the lesion was almost closed, as seen in Figure 27 (page 35). Six months post-treatment, the patient was reported to be healthy and in remission.

However, the collaboration ended abruptly prior to the Covid outbreak in December 2019, with no communication with the team in China during or following the pandemic. Although this prevented the Company from obtaining the medical records, and this trial consisted of a single data point, the Company believes that it can replicate the clinical results in other patients using NK101. If successful in doing so, NK101 could represent a breakthrough therapy for the treatment of multiple forms of cancer.

Figure 27
 sNK EFFECT ON ORAL LESION (NON-HODGKINS LYMPHOMA)

Pre-Treatment	14-Days Post Treatment
Oral Lesion Present	Supercharged NK Cells Eliminated Lesion



Source: NKore BioTherapeutics, LLC.

NK101 Clinical Use (Cancun, Mexico)

NK101 has not been approved for clinical use in the U.S. NKore anticipates filing its pre-Investigational New Drug submission with the FDA in 2024 and, subject to the guidance received from the FDA, file the IND application for NK101 in late 2024 or 2025. The approval of the IND application by the FDA is required before NKore can commence human clinical trials in the U.S.

As the Company seeks to translate the positive preclinical results into patients, and pending the approval of its IND application, NKore has commenced clinical use outside the U.S. The Company's efforts are being conducted in Cancun, Mexico, with a focus on the clinical use of NK101 as a palliative treatment option for patients with metastatic or unresectable cancers for which standard curative measures do not exist or are no longer effective.

NK101 Cancun Overview

Patients that have failed other treatment options may elect palliative treatment with sNK cells at the Rehealth Clinic in Cancun, a licensed treatment facility with considerable experience administering cellular therapies and other forms of infusion therapy, including autologous NK cell therapies. NKore intends to engage a third-party clinical research organization (CRO) to assist it in tracking patient outcome data with respect to the treatment. The Company's goal is to demonstrate the clinical safety of NK101 as a palliative treatment option and use that safety data to support its IND application in an effort to obtain FDA approval to commence clinical trials in the U.S. In addition, promising efficacy data could allow the Company to seek accelerated regulatory review from the FDA as part of the IND submission process.

NKore engaged a licensed cell-based contract manufacturer in Cancun, Mexico to collect and process allogeneic NK cells from qualified donors. In October 2023, the contract manufacturer successfully completed the activation and expansion process under cGMP conditions to produce NK101 for clinical use. The Company believes that this confirms its ability to successfully transfer the technology from an academic laboratory at UCLA to a cGMP manufacturing facility to produce clinical doses.

The produced sNK cells were used to treat the first two patients in Cancun, with the therapy commencing on December 5, 2023. The Company is now compiling the pre and post-infusion clinical data to evaluate changes in the patients' immune function and response to therapy. The two patients selected were:

Patient 1: A 64-year-old male diagnosed with a form of non-Hodgkin's lymphoma (Chronic Lymphocytic Leukemia [CLL]) three years ago. He completed one round of chemotherapy to reduce the tumor burden and was taking check point inhibitors twice daily. Notwithstanding that treatment, he was informed by his clinical team at the Mayo Clinic in Jacksonville, Florida that he had a genetic mutation which limits his ability to respond to conventional therapy that changed his prognosis from good to poor. After researching NKore's technology, members of his clinical team supported his decision to travel to Cancun to receive the experimental therapy.

Patient 2: Ms. Ryan's (NKore's co-founder and CCO) daughter Sophie, an 11-year-old girl who was diagnosed with an incurable Grade 1 Optic Pathway Glioma brain tumor when she was 8 months old. Sophie has failed seven different chemotherapy and clinical trial protocols, had 11 surgeries including five 5 brain surgeries, and her tumor had not shrunk in over five years. Sophie received her father's IL-2 activated NK cells, a therapy that is significantly less cytotoxic than NKore's sNK cells, with the tumor shrinking for 16 months post therapy. Despite this success, Sophie's tumor is still present. Accordingly, in an effort to kill the remaining tumor cells and eliminate any remaining disease, she became the second patient to receive NK101.

If the clinical use provides promising early safety data, NKore intends to use that data as part of its IND submission to the FDA. In addition, promising efficacy data could allow the Company to seek accelerated regulatory review with the FDA. According to the Company, the FDA has recognized that regenerative medicine is a rapidly expanding field that has the potential to treat serious conditions more effectively than conventional therapies. To facilitate the development of these advanced therapies, including various cell and gene therapies, the FDA has implemented programs to accelerate the regulatory review and approval process for products that qualify for designation as "regenerative medicine advanced therapy" (RMAT). Given NKore's intended focus on the most aggressive forms of cancer with a five-year survival rate of less than 5% when diagnosed at later stages, it plans to request such designation in connection with any subsequent IND submission pending positive early clinical results that would support such designation. If granted, the accelerated regulatory review should allow the Company to commence clinical trials in the U.S. more quickly.

Treatment of the first two patients is a significant milestone for NKore. With limited funding and a small team, the Company has been able to demonstrate the ability to transfer the cell activation and expansion process from a research lab to a cGMP manufacturing facility and, more importantly, confirm the safety profile of the cells in patients. While much more patient data is needed to confirm the clinical safety of NK101, the early data is positive and, absent an unexpected negative safety finding, it should allow NKore's to expand the clinical use as a palliative treatment option in Cancun. NKore is scheduled to commence the next NK101 production run in mid-April and should have product available for the treatment of the next cohort of cancer patients in late June.

NK101 Cancun Clinical Use Update

Blood tests (at 7, 14, 30, 60 and 90-days following NK101 administration) indicate a positive immune response with expected tapering over time for both patients. In addition, NK101 displayed an excellent safety profile, with neither patient experiencing any adverse side effects or any type of discomfort after receiving the therapy.

Patient 1 Results

Despite 3-years of targeted therapy, Patient 1 never achieved remission, with tumor cell infiltration in the bone marrow measuring 20% prior to treatment with NK101. In addition to an elevated B-cell count, the patient suffered with daily body pain, exhaustion, fogginess, and overall discomfort. Patient 1 received a single infusion of approximately 350 million NK101 cells on December 5, 2023, with post-infusion blood work showing a positive early immune response and no adverse safety events. The 90-day review of the post-infusion test results provide early signs of partial remission after only one treatment, with validated data points confirming NK101's ability to target and spontaneously kill the tumor cells that had infiltrated the bone marrow; reverse disease progression; and restore partial immune function. The early clinical data is consistent with Dr. Jewett's preclinical results.

Data Point 1: Bone marrow aspirate

Prior to his infusion with NKore’s therapy, Patient 1’s bone marrow aspirate showed tumor cell infiltration totaled 20% after 3 years of treatment with chemotherapy and a BTK inhibitor. Following a single infusion of NK101, bone marrow aspirate collected at day 58 showed 75% reduction in tumor cell infiltration in bone marrow with only 5% minimal residual disease remaining. Figure 28 shows the pathologists final diagnosis and interpretation for both bone marrow aspirate tests.

Figure 28

CANCUN TRIAL - BONE MARROW ASPIRATE RESULTS

Bone Marrow Aspirate / August 21, 2023

Interpretation - FINAL DIAGNOSIS

Bone marrow aspirate and biopsy: Slightly hypercellular bone marrow with chronic lymphocytic leukemia/ small lymphocytic lymphoma, 20% of the marrow space.

Bone Marrow Aspirate / February 2, 2024

Interpretation - FINAL DIAGNOSIS

Bone marrow aspirate: Consistent with minimal residual chronic lymphocytic leukemia (5%).

Bone marrow biopsy: In accord with above.

Source: NKore BioTherapeutics, LLC.

Data Point 2: Chest CT scans

CT chest scans with IV contrast were performed two months post NK101 cell infusion (February 13, 2024), with results compared to previous CT scan performed pre-infusion (May 31, 2023). Results showed a significant decrease in the size of the lymph nodes in the abdominal cavity, reflecting the smallest measurements for the patient since diagnosis and treatment with conventional therapy. As seen in Figure 29, lymph nodes in the abdomen with tumor cells decreased in size from 21% to 70%. Figure 30 (page 38) shows the CT scan results for both the right external iliac lymph node (reduction of 66%) and inferior right external iliac lymph node (reduction of 70%). The treating oncologist stated that the patient is showing early signs of partial remission and immune restoration.

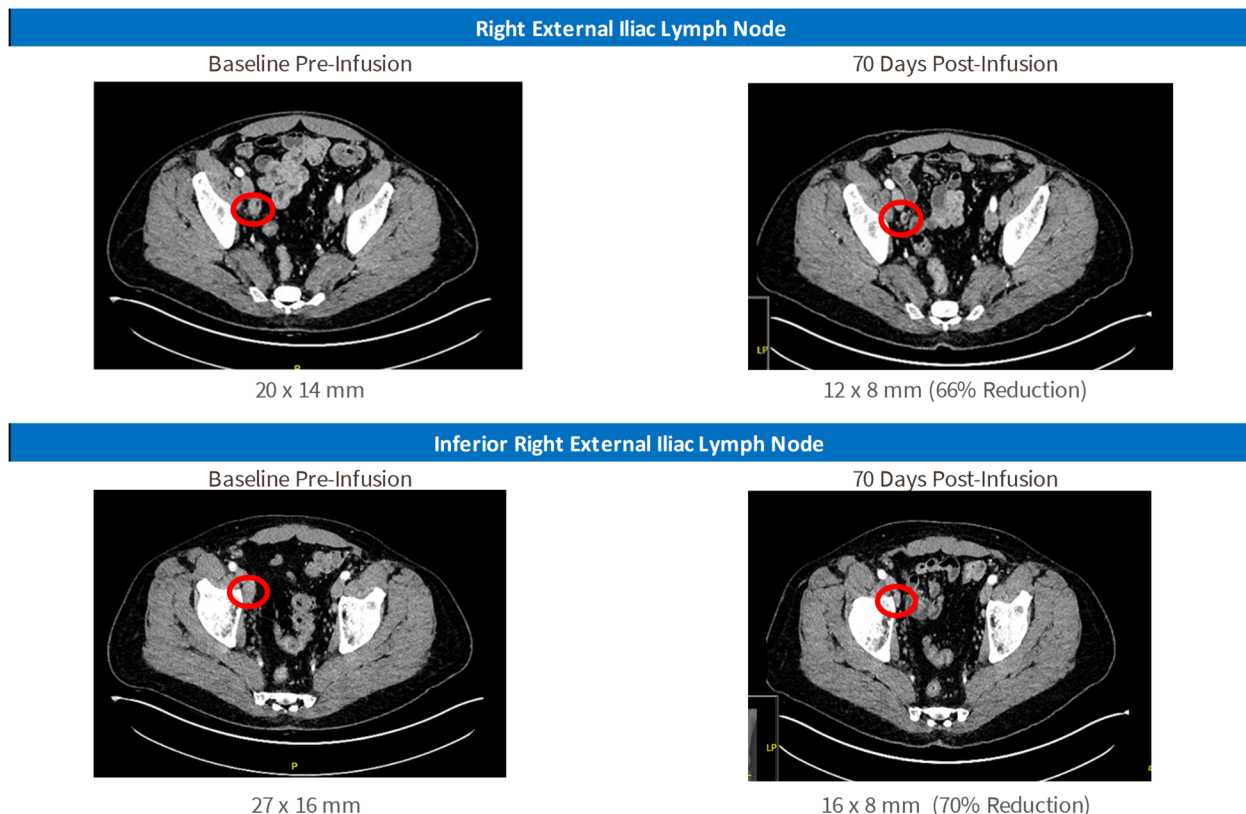
Figure 29

CANCUN TRIAL - CT SCAN RESULTS

LYMPH NODE LOCATION	Previous Measurements	Current Measurements	Reduction Percentage
Left Periaortic Node	26 x 16mm	18 x 8mm	65%
Left Mesenteric Node	19 x 12mm	15 x 12mm	21%
Adjacent Left Mesenteric Node	15 x 8mm	13 x 7mm	24%
Right External Iliac Lymph Nodes	20 x 14mm	12 x 8mm	66%
Left External Iliac Lymph Nodes	27 x 16cm	16 x 8mm	70%
Left External Iliac Lymph Nodes	9 x 5mm	6 x 5 mm	33%

Source: NKore BioTherapeutics, LLC.

Figure 30
 PATIENT 1 CT SCAN RESULTS



Source: NKore BioTherapeutics, LLC.

Data Point 3: Immune cell proportions in the peripheral blood mononuclear cells (PBMCs)

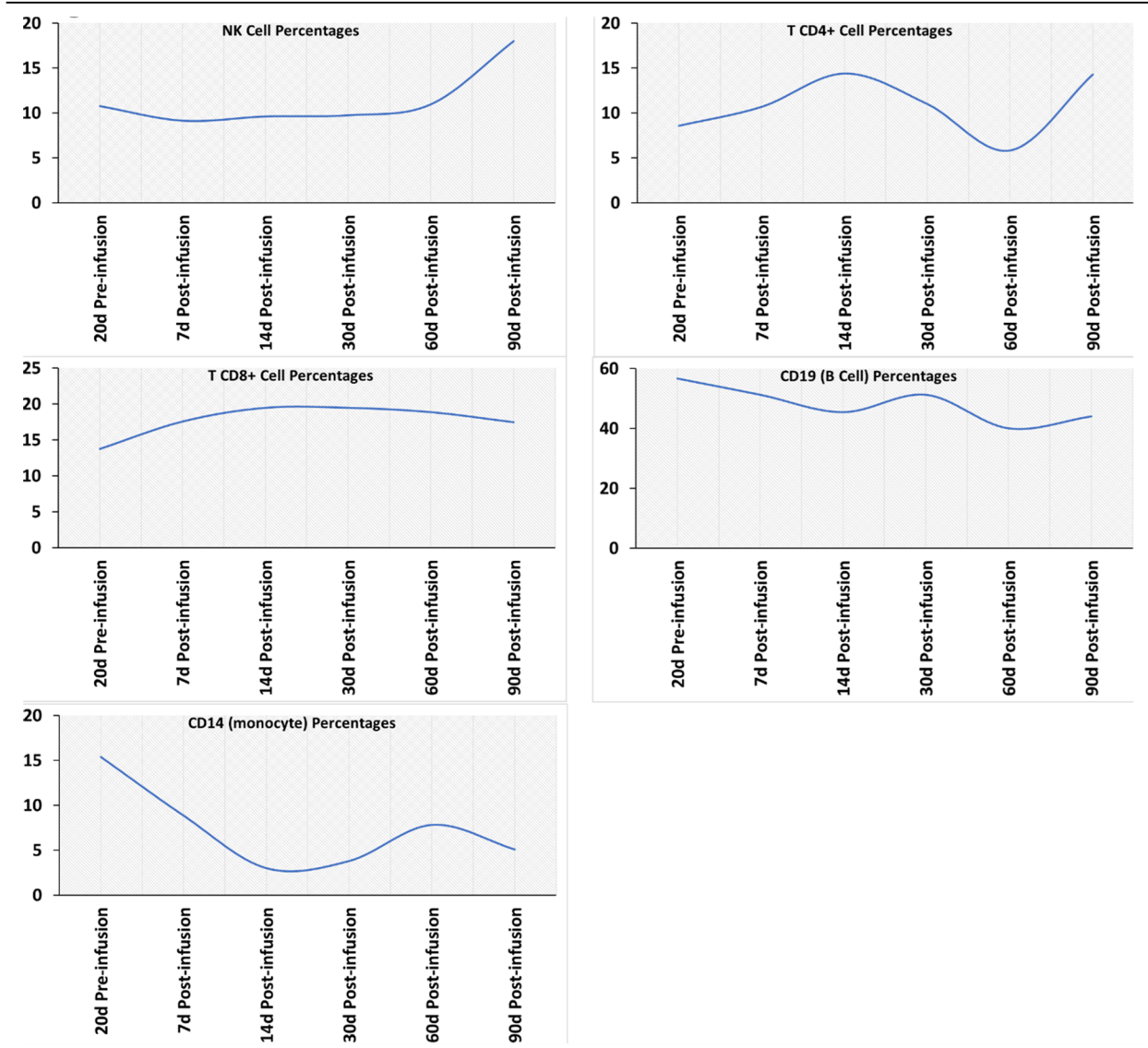
To evaluate the immune response to therapy, NK cell percentages and NK cell activity found in the peripheral blood mononuclear cells (PBMCs) were assessed at regular intervals. See Figure 31 and Figure 32 (page 39). In comparing the pre-infusion and post-infusion results, even though there were fluctuations in the percentages of NK cells, in general there was a tendency for an increase in the NK cell subset. In fact, when the Company initially assessed the NK cell function for Patient 1 the year prior to receiving the therapy, he had less than 2% NK cells with defective NK cell function. Twenty days pre-infusion his NK cell count had increased to 10.8% likely due to other treatments, and on the 90-day post-infusion mark the patient had 18% NK cells in his PBMCs.

Figure 31
 IMMUNE CELL PERCENTAGES

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
NK cells	10.8	9.18	9.65	9.78	11	18
T CD4+	8.58	10.69	14.4	11	5.83	14.3
T CD8+	13.8	17.6	19.5	19.5	18.9	17.5
CD19 (B cells)	56.7	51.3	45.5	51.3	40.1	44.1
CD14 (Macrophages)	15.4	8.86	3	3.8	7.83	5.09

Source: NKore BioTherapeutics, LLC.

Figure 32
 IMMUNE CELL PERCENTAGES



Source: NKore BioTherapeutics, LLC.

Data Point 4: IFN- γ secretion and cytotoxic activity levels of PBMCs and NK cells

The Company also measured the effect of NK101 on IFN- γ secretion levels through a proprietary test developed by Dr. Jewett and part of the Company’s cell diagnostic screening portfolio (highlighted on page 47). Results show that the use of NK101 leads to higher levels of IFN- γ secretion levels. This is of significance as IFN- γ secretion is linked to a positive immune response to cancer, increased cytotoxic activity, as well as differentiation of the CSCs to reduce the risk of metastasis.

IFN- γ production is a reliable marker for measuring the activation of PBMCs—a variety of specialized immune cells which includes lymphocytes, such as T-cells and NK cells. Detection of T-cell and NK cell activation is considered a functional marker to measure cellular immune response against a specific antigen, such as cancer. As seen in Figure 33 (A and B) and Figure 34, the use of NK101 (denoted as IL2+sAJ4) resulted in higher levels of activation for both PBMCs and NK cells, even 90 days post-treatment, as measured by IFN- γ secretion.

Figure 33 (A)
PBMC ACTIVATION STATUS (INFg RELEASE, pg/mL)

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt	16	0	0	0	0	0
IL2	29.7	0	0	99.1	0.9	0
IL2+aCD16	58.8	0	0	22.4	15	93.3
IL2+aCD3/28	67.3	55	29.1	566	95	585.1
IL2+sAJ4	486	487	167	1844	636	1607.3

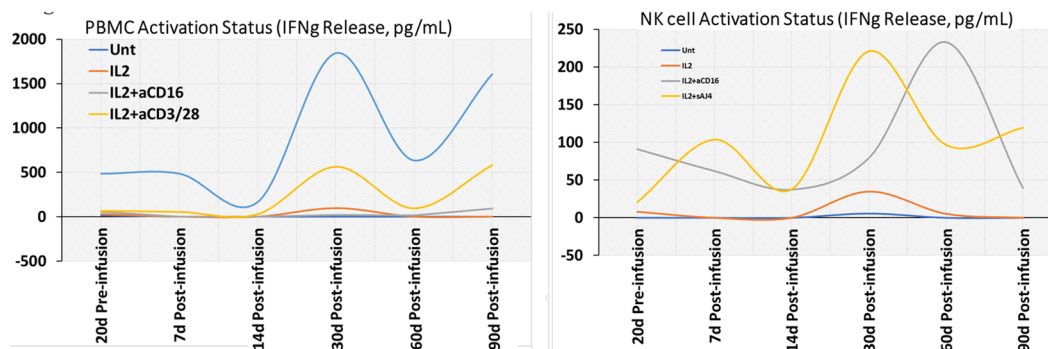
Source: NKore BioTherapeutics, LLC.

Figure 33 (B)
NK CELL ACTIVATION STATUS (INFg RELEASE, pg/mL)

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt	0	0	0	5.8	0	-
IL2	8.1	0	0	35	5.4	0
IL2+aCD16	91	62	37.3	79	233	39.52
IL2+sAJ4	21	104	38	221	97	119.6

Source: NKore BioTherapeutics, LLC.

Figure 34
PBMC ACTIVATION STATUS (INFg RELEASE, pg/mL)



Source: NKore BioTherapeutics, LLC.

The activation of these immune cells, coupled with the presence of IFN- γ , which exerts a direct tumor-killing function by promoting an inflammatory immune response and regulating the adaptive immune response to cancer, results in increased cellular cytotoxicity, an important effector mechanism of the immune system to combat cancer. To measure cytotoxicity, a Cr-51 release assay was used, which provides an accurate quantification of cytotoxicity of T-cells and NK cells. Target cells are labeled with radioactive chromium and co-cultured with effector cells. Upon cell lysis, the loss of cell membrane integrity triggers the extracellular release of Cr-51, which is then measured. As seen in Figure 35 (A and B), and Figure 36, use of NK101 resulted in higher cytotoxic activity using IL2 + sAJ4 at each post-infusion time period for the PBMCs and higher cytotoxic activity of the NK cells at day 14 and 60, with a slight decline at day 90.

Figure 35 (A)
CYTOTOXIC ABILITY OF ALL PBMCs (Cr51 Release)

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt	1.3	1.83	4.23	4.25	5.19	2.39
IL2	12.2	13	23.4	22.5	38	16.4
IL2+aCD16	2.9	4.5	0.5	0.9	11.8	9.21
IL2+aCD3/28	18.2	13	46	53	54	42.5
IL2+sAJ4	11	16.2	27	35	42.5	23.5

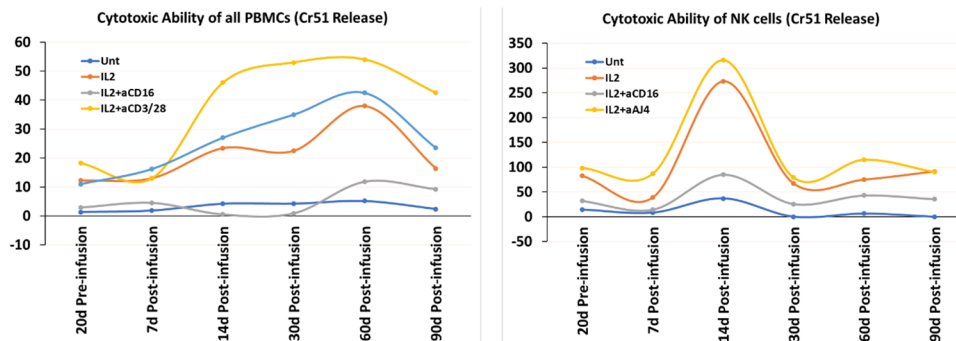
Source: NKore BioTherapeutics, LLC.

Figure 35 (B)
CYTOTOXIC ABILITY OF NK CELLS (Cr51 RELEASE)

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt	14.4	8.3	37	0.1	6.3	-
IL2	82.7	39	273	67.3	75	91.5
IL2+aCD16	32	14.5	85	25.8	43	35.8
IL2+aAJ4	98.4	87	316	79	115	90.18

Source: NKore BioTherapeutics, LLC.

Figure 36
CYTOTOXIC ABILITY OF ALL PBMCs (Cr51 Release)



Source: NKore BioTherapeutics, LLC.

In terms of other key immune cell subsets, there is also some elevation of CD8+ T cells. Of significance is the decrease in CD19 (B-cell) in Patient 1. Chronic Lymphocytic Leukemia, or CLL, is a B-cell malignancy characterized by elevated B-cell counts. Accordingly, the reduction in the CD19 B-cells from 56.7% pre-infusion to 44.1% at day 90 post-infusion, a 22% decline, reflects a positive immune response. Even more positive is the 67% decline (from 15.4% to 5.09%) in monocytes at day 90. The monocytes have a significant mechanistic reason for the NK cell activation and decrease in tumor burden. Of interest in evaluating the test results is the effect of NK101 in increasing the functional activation of autologous NK cells when patient immune cells were treated with IL-2 plus anti-CD3/anti-CD28, implicating the role of T-cells in NK cell activation. Post-infusion testing is continuing in an effort to measure the persistence of the immune response and to further correlate the changes to the immune cell subsets.

Patient 2 Results

Patient 2 was diagnosed with an incurable Grade 1 Optic Pathway Glioma brain tumor at 8 months old and was unable to stop disease progression despite multiple chemotherapy treatments and brain surgeries over a seven-year period. As described on pages 31-32, Patient 2 was able to achieve tumor shrinkage following two infusions of IL-2 activated NK cells that Dr. Jewett has confirmed in preclinical models are significantly less effective than NKore’s NK101 cells. Despite this success, the tumor was still present, with the patient otherwise healthy but with remaining stable disease.

The patient received a single infusion of approximately 100 million NK101 cells on December 5, 2023, with no adverse events or side effects resulting from therapy. Blood draws following therapy continue to show a positive immune response and a significant increase in cell activation, IFN-γ release, and cytotoxicity activity.

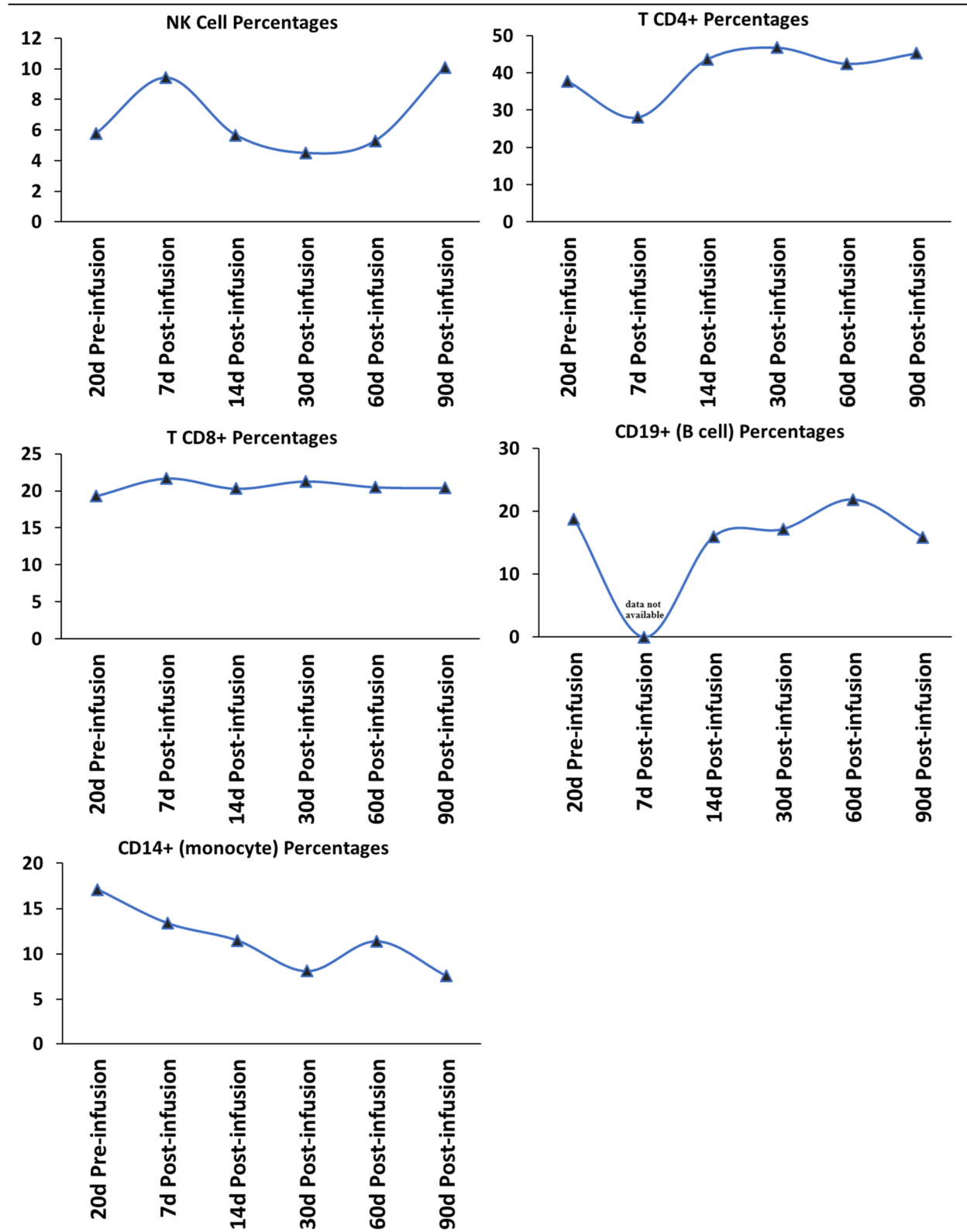
Patient 2 displayed positive patient trends in the blood test results. In fact, a significant drop in monocytes was evident in the patient while the NK cell percentages remained relatively consistent with some elevations at different time points (Figure 37 and Figure 38, [page 43]). Her NK cells exhibited higher cytotoxicity and secretion of IFN-γ at certain days post-infusion compared to pre-infusion. Although the clinical team is still testing post-infusion blood, the trends are encouraging and likely point to the restoration of the patients’ NK cell function post-infusion. In *in vitro* studies the majority of the sNK cells survived less than 60 days, so it is unlikely that all NK101 cells have survived 90 days post-infusion, suggesting some restoration of normal immune function.

Figure 37
 IMMUNE CELL PERCENTAGES

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
NK cells	5.79	9.42	5.67	4.5	5.29	10.1
T CD4+	37.8	28.1	43.7	46.8	42.5	45.3
T CD8+	19.3	21.7	20.3	21.3	20.5	20.4
CD19 (B cells)	18.8	-	16	17.2	21.9	15.9
CD14 (Macrophages)	17.1	13.4	11.5	8.12	11.4	7.58

Source: NKore BioTherapeutics, LLC.

Figure 38
 IMMUNE CELL PERCENTAGES



Source: NKore BioTherapeutics, LLC.

The use of NK 101 resulted in increased cell mediated IFN- γ production, which led to antiviral, immunoregulatory and anti-tumor properties, and indicated a positive immune response. Like Patient 1, the use of NK101 (denoted as IL2+sAJ4) resulted in higher levels of activation for both PBNCs and NK cells, even 70 days post treatment, as measured by IFN- γ secretion as seen in Figure 39 (A) and (B), and Figure 40.

The use of NK101 also resulted in increased cellular cytotoxicity, with the 70-day post infusion results reflecting a substantial increase in the cytotoxicity of the patient’s NK cells (Figure 41 (A) and (B), and Figure 42 [page 44]).

Despite the results indicating a positive immune response and increased cytotoxic activity, the clinical team believes that due to the location and nature of the disease, observable changes to tumor mass will require additional time. Additional patient follow-up, including a second post-infusion MRI scan, will be completed in the next 45 days.

Figure 39 (A)
 PBMC ACTIVATION STATUS/IFN γ RELEASE - PATIENT 2

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
IL2	0	5.2	0	0	0	0
IL2+sCD16	123.3	14.8	0	37.5	84.5	407
IL2+sCD3/28	93.4	927.8	0	33.05	0	170
IL2+sAJ4	241.8	1470.6	1029.7	811.03	1857.17	2216.6

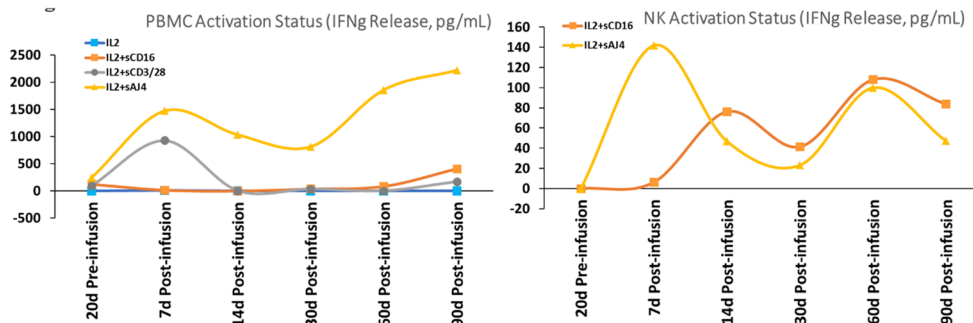
Source: NKore BioTherapeutics, LLC.

Figure 39 (B)
 NK cell ACTIVATION STATUS/IFN γ RELEASE - PATIENT 2

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
IL2+aCD16	0	6.27	76.23	41.4	108	83.8
IL2+sAJ4	-	142	47	23.1	100	47.29

Source: NKore BioTherapeutics, LLC.

Figure 40
 PBMC ACTIVATION STATUS/NK cell ACTIVATION STATUS/IFN γ RELEASE - PATIENT 2



Source: NKore BioTherapeutics, LLC.

Figure 41 (A)
 CYTOTOXIC ABILITY OF ALL PBMCs

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt	2	6	4	1.42	3.6	3.96
IL2	7.07	10.1	12	4.29	15	21.6
IL2+aCD16	3.88	8.11	4	1.41	14	7.6
IL2+sCD3/28	8.71	16	8.2	5.5	5.6	28
IL2+sAJ4	5.68	10.5	44.5	5	15.9	20.5

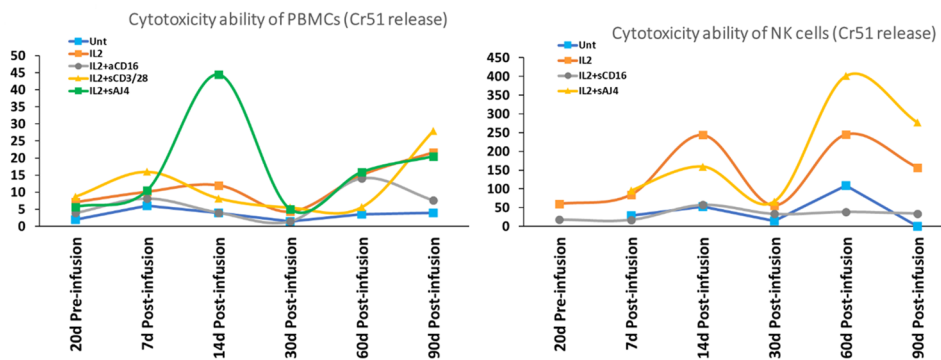
Source: NKore BioTherapeutics, LLC.

Figure 41 (B)
 CYTOTOXICITY - NK cells

	20d Pre-infusion	7d Post-infusion	14d Post-infusion	30d Post-infusion	60d Post-infusion	90d Post-infusion
Unt		29	53	15	109	-
IL2	59.4	84	243.7	55.5	245	157
IL2+sCD16	17.82	17	57	33	38.33	34
IL2+sAJ4		95.46	159.5	66.2	401.6	277

Source: NKore BioTherapeutics, LLC.

Figure 42
 CYTOTOXICITY ABILITY OF PBMCs (Cr51 release)/CYTOTOXICITY ABILITY OF NK cells (Cr51 release)



Source: NKore BioTherapeutics, LLC.

NK101's Cancun Clinical Use Future Plans

Following positive initial data on both patients, NKore is planning to expand NK101's clinical use in Cancun. NKore is scheduled to start the next NK101 production run in mid-April and should have product available for the treatment of the next cohort of cancer patients in late June or early July. The Company is currently working with its clinical and medical advisory team to confirm the patient selection criteria for other patients to receive treatment in Cancun.

NKore is seeking to identify a second patient with CLL lymphoma that desires to undergo treatment in Cancun to expand its finding on the disease beyond a single data point. In addition, since preclinical testing has shown NK101's effectiveness against the most aggressive forms of cancer, the Company also intends to target these disease states. The potential ability to show any type of positive effect in treating cancers where no therapy has proven successful (i.e., breakthrough therapy) could facilitate a request for accelerated FDA regulatory review and, more importantly, improve clinical outcomes or improve the quality of life for patients that have no effective treatment options today.

Targets include pancreatic cancer, as well as glioblastomas, with preclinical data showing success for both. In addition, if additional studies confirm the ability of NK101 to consistently cross the **blood brain barrier** without increasing the risk of a serious adverse safety event, that would expand the potential to eventually use NK101 in other types of brain cancers, such as diffuse intrinsic pontine glioma (DIPG). DIPG is an aggressive pediatric brain tumor with no effective treatment, resulting in high morbidity and mortality, with a median survival time from diagnosis of less than a year.

NK Cell Diagnostics

In addition to the activation method for NK101, NKore's IP portfolio includes a companion cellular-based diagnostic screening platform to measure the cellular function of the immune system to assess the patient's response to therapy and assist clinicians develop better personalized treatment plans. When commercially available, NKore's screening tests will seek to evaluate the quality of immune function at a cellular level to establish a baseline to better predict or detect the early onset of disease and measure changes to immune function over time. The goal is to identify changes to immune function prior to the onset of disease to allow clinicians to intervene earlier and seek to restore immune function to prevent, not reverse, disease progression. If, as the Company believes, NK101 proves to have a unique safety profile and can act as a catalyst to restore immune function, its use as a monotherapy could then provide a novel interventional therapeutic approach to prevent or delay the onset of disease. For a patient that has a family history of cancer and DNA biomarkers that indicate the presence of circulating tumor cells in the body, testing and monitoring his or her immune function will be essential in developing early intervention strategies.

The full line of planned tests for both therapy assessment and early detection are listed below (availability TBD):

- NK Cell Test/tumor killing assay
- NK proliferation
- NK expansion with monocytes
- Cytokine Release
- Surface Analysis / 1 Expressions.

Investment Highlights

- NKore Biotherapeutics, LLC (“NKore” or “The Company”) is a biotherapeutics company focused on the early detection, prevention, and treatment of cancer. The Company’s technology platform is based on a proprietary method of activating allogeneic natural killer (NK) cells, creating Supercharged Natural Killer (sNK) cells used as a novel oncology immunotherapy technology platform.
- The technology was developed by Dr. Anahid Jewett, NKore’s co-founder and Chief Scientific Advisor. Based on preclinical results, the Company believes that Dr. Jewett’s 30-plus years researching NK cell function has resulted in the development of a novel and effective cancer immunotherapy. NKore’s current focus is to translate and replicate the positive preclinical results into human clinical trials to obtain marketing approval.
- NK cell therapy has significant advantages against competing alternatives. Since NK cells do not need to be genetically engineered to recognize cancer cells, it simplifies the lengthy and costly manufacturing process normally associated with many other forms of immunotherapy. In addition, NK cell therapy provides a better safety profile compared to other forms of cancer treatment, such as chemotherapy and radiation, which are normally associated with severe toxicities and can reduce physical strength and impair immune response.
- NK cells’ ability to identify and spontaneously kill cancer cells allows them to play a critical dual role in the prevention and treatment of cancer. NK cells cytotoxic activity not only attacks infected and cancerous cells in the tumor, but also helps to eliminate poorly differentiated cancer stem cells (CSCs), a subpopulation of tumor cells displaying self-renewal ability and resistance against conventional cancer therapies. CSCs presence is recognized as a crucial factor contributing to tumor progression, recurrence, and metastasis.
- NK cells also play a dual role in the elimination of CSCs. NK cells have been shown to selectively kill CSCs as well as induce differentiation of these cells through the release of gamma interferon (IFN- γ), eliminating their self-renewal ability and making them more susceptible to other cancer treatments, leading to their elimination.
- However, despite NK cells’ key role in controlling cancer, the tumor microenvironment (TME) has been shown to suppress both the number and the function of NK cells, diminishing IFN- γ secretion, reducing cytotoxicity against cancer cells, and adversely influencing other anti-cancer processes.
- Working with Dr. Jewett, NKore has developed NK101, a cellular-based immunotherapy that has proven effective in preclinical models in the treatment of both solid tumors and hematologic malignancies. The proprietary NK cell activation method generates more robust and effective NK cells that better withstand the suppressive TME, enhancing their cytotoxic function and increasing their secretion of functional IFN- γ .
- Preclinical studies have demonstrated NK101’s ability to stop or reverse disease progression as well as to reduce the metastatic potential of tumor cells in many forms of cancer, including glioblastoma, pancreatic, melanoma, oral, lung, and ovarian cancer, as well as hematologic malignancies.
- NKore has commenced clinical use in Cancun, Mexico, using NK101 as a palliative treatment option for patients with metastatic or unresectable cancers that have failed conventional treatment options. Initial clinical use included two patients that were treated in an effort to reduce the pain and discomfort associated with their diseases and demonstrate the clinical safety of NK101. With the treatment of additional patients, the Company plans to use the data to support its IND submission with the FDA.
- While only limited clinical data is available, NK101 appears to have a solid safety profile, with neither patient experiencing any adverse side effects or discomfort after receiving the therapy. Initial results look promising, demonstrating the ability of NK101 to target and spontaneously kill at least some tumor cells, reverse disease progression, and begin to restore immune function, similar to the preclinical results achieved by Dr. Jewett.

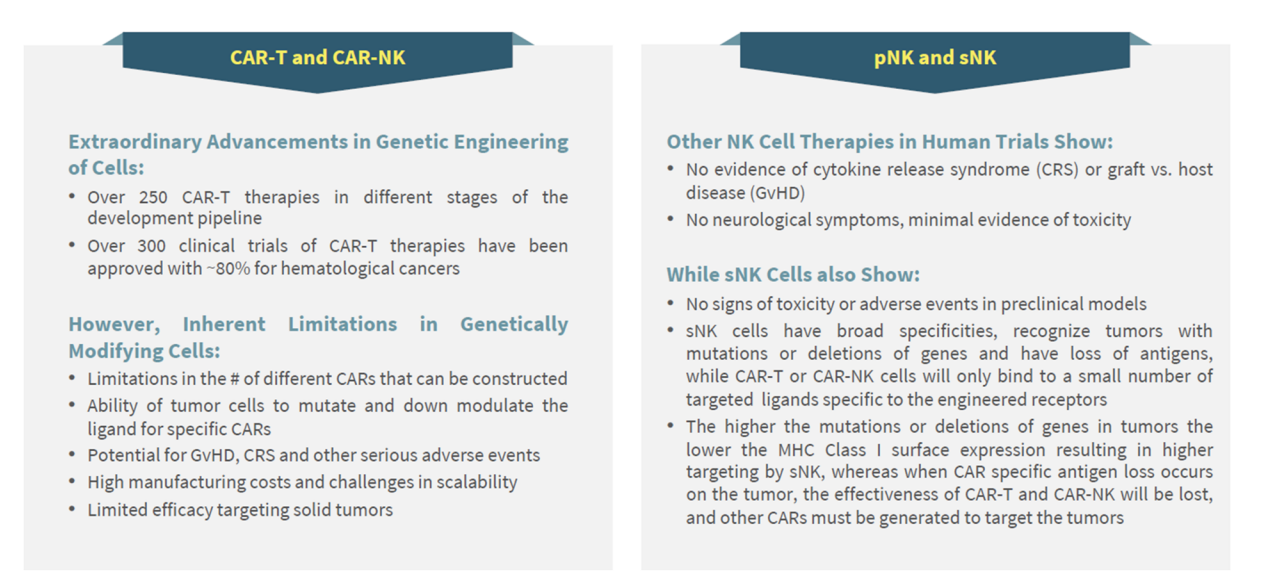
- At 60 days post-infusion, Patient 1 (a 64-year-old male diagnosed with a form of non-Hodgkin's lymphoma and presenting with a genetic mutation which limits his ability to respond to conventional therapy) achieved a 75% reduction in tumor cell infiltration in his bone marrow, as well as a significant reduction in the size of enlarged lymph nodes in his abdominal cavity. The 90-day review of the post-infusion test results suggest early signs of partial remission after only one treatment.
- Early safety data for Patient 2, an 11-year-old girl diagnosed with an incurable Optic Pathway Glioma brain tumor, is also positive. Blood draws following therapy continue to show a positive immune response and a significant increase in cell activation, IFN- γ release, and cytotoxic activity. Given the location and nature of this tumor, the Company believes that it is too early to assess a clinical response to therapy.
- To support its immunotherapy initiative, NKore also intends to commercialize a companion proprietary cell-based diagnostic screening platform to monitor the patient's immune function to assess a patient's response to therapy and to assist clinicians in the development of better personalized treatment plans.
- Since formation, NKore has completed funding activities totaling approximately \$3.2 million.

Competition

As NKore continues to develop and seeks to commercialize its products, the Company may encounter competition from other pharmaceutical and biotechnologies companies, including those that currently market approved immunotherapies for the indications the Company is targeting, as well as those developing new and innovative therapeutic treatments, including other forms of immunotherapy or NK cell therapy. Potential competitors may also include academic institutions, government agencies, and other public and private research organizations that participate in the research of NK cell technologies and other forms of immunotherapy, as well as those who seek to establish collaborative arrangements for research, development, manufacturing, and commercialization.

According to the Company, the metabolic structure of its proprietary sNK cells have a unique safety profile, manufacturing cost, and scalability potential when compared to other immunotherapies, such as CAR-T or CAR-NK. Competing NK cell therapies generally focus on cord blood, iPSC derived, or autologous cell sources that limit scalability and effectiveness, with the majority of them focusing on treating hematologic cancers. In addition, NKore’s non-engineered sNK cells demonstrate significantly higher cytotoxicity and secretion levels of IFN-γ than other activated NK cell therapies tested by Dr. Jewett. Figure 43 provides a comparison overview of the different immunotherapies.

Figure 43
 IMMUNOTHEPY COMPETITION COMPARISON



Source: NKore BioTherapeutics, LLC.

The accompanying section provides profiles of potential competition that the Company may face as it seeks to enter the market. It is not intended to be an exhaustive collection of potential competitors, however, it is believed to be a sample of the type of competition the Company may face as it strives to commercialize its technologies and product candidates.

Celularity Inc. (CELU-NASDAQ)

Celularity is a biotechnology company developing off-the-shelf placental-derived allogeneic cell therapies, including genetically modified and unmodified NK cells, engineered T-cells, including CAR-T cells, and mesenchymal-like adherent stromal cells (ASCs), targeting indications across cancer, immunologic, infectious, and degenerative diseases. Its NK cell portfolio includes CYNK-001 (placental-derived natural killer cells), in a Phase 1-2 trial for treatment of acute myeloid lymphoma (AML) and also being investigated for multiple myeloma (MM) and

glioblastoma multiforme (GBM); CYNK-101, genetically modified NK cells as a combination treatment for multiple cancer indications; and a CAR-NK platform against hematological and solid tumor targets under pre-clinical evaluation. Celularity is headquartered in Florham Park, New Jersey.

Fate Therapeutics, Inc. (FATE-NASDAQ)

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of off-the-shelf induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients with cancer and autoimmune disorders. The company is developing a pipeline of iPSC-derived therapies for the treatment of cancer, including: FT576 for multiple myeloma (Phase 1) and FT522 for B-cell lymphoma (Phase 1), as well as a preclinical program for FT522 in autoimmune disease. Fate Therapeutics is also developing CAR-T therapies, including FT819 (B-cell malignancies) and FT825 (solid tumors), both in Phase 1 studies. The company has research collaborations with the University of Minnesota and Oslo University Hospital, and is headquartered in San Diego, California.

Glycostem Therapeutics B.V.

Glycostem is focused on developing stem cell-derived allogeneic NK cells as a medicinal asset in the fight against hematological indications and solid tumors, with the company's investigational therapies to be used as a standalone and add-on therapy, allowing multiple treatment options. Glycostem's first-generation NK cell-based immunotherapy platform—oNKord®—is being evaluated for AML (Phase 1—Orphan Drug Designation), as well as in pre-clinical programs for solid and metastatic solid tumors. The company is also developing a CAR-NK technology platform—ViveNK™—currently in pre-clinical assessment for solid tumors. Glycostem has research collaboration agreements with medac GmbH, an international pharmaceutical company based in Germany, as well as inno.N, a Korean pharmaceutical company. Glycostem headquarters are located in Oss, the Netherlands.

Nkarta, Inc. (NKTX-NASDAQ)

Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf NK cell therapies. By combining its cell expansion and cryopreservation platform with proprietary cell engineering technologies and CRISPR-based genome engineering capabilities, Nkarta is building a pipeline of future cell therapies engineered for deep therapeutic activity and intended for broad access in the outpatient treatment setting. The company's clinical programs include NKX101 in Phase 1 trials for AMLs (and preclinical trials for solid tumors); and NKX019 in Phase 1 trials for B-cell malignancies (i.e., non-Hodgkin lymphoma [NHL], chronic lymphocytic leukemia [CLL] or B cell acute lymphoblastic leukemia [B-ALL]). The company is headquartered in San Francisco, California.

Sanofi (SNY-NASDAQ)

Sanofi is a global healthcare company operating across more than 100 countries, providing therapeutic options in oncology, immunology and inflammation, neurology, rare blood disorders, rare diseases, and vaccines. Its oncology pipeline continues to build on Sanofi's emerging presence in immuno-oncology, as it considers NK cell therapies a key pillar of its oncology pipeline. In this area, Sanofi has broadened its position in the NK cell space by three key initiatives: (1) research collaboration with Innate Pharma, in which Sanofi is using Innate's B7H3 ANKET (antibody-based NK Cell Engager Therapeutics) platform to develop cancer-fighting drugs, including product candidates SAR443579 in Phase 1 trials for AML, and SAR445514 in Phase 1 trials for refractory multiple myeloma; (2) research collaboration with Scribe Therapeutics, in which Sanofi will apply Scribe's CRISPR genome editing technologies, designed to enable genetic modification of novel natural killer (NK) cell therapies for cancer; and (3) the 2021 acquisition of Kiadis Pharma and its off-the-shelf allogeneic NK cell technology platform, with Sanofi planning to develop this technology alone (as is the case of its product candidate SAR445419 in Phase 1 trials for AML) or in combination with Sanofi's existing pipeline and platforms. Sanofi is headquartered in Paris, France.

Risks and Disclosures

This Executive Informational Overview[®] (EIO) has been prepared by NKore Biotherapeutics, LLC (“NKore” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. The information in this Executive Informational Overview (EIO) relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in NKore’s statements on forms filed from time to time.

The content of this report with respect to NKore Biotherapeutics has been compiled primarily from information available to the public or released by the Company through news releases and other filings. NKore Biotherapeutics is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by NKore Biotherapeutics or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its Agreement, CRA has been compensated by the Company in cash of fifty thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about NKore’s business, as described below. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to NKore Biotherapeutics or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, NKore’s business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved of investing in the Company, as well as for copies of this report, please contact NKore by emailing Tracy Ryan at tryan@nkore.com.

RISKS RELATED TO NKORES’ BUSINESS AND INDUSTRY

NKore is dependent on the success of its product candidate, NK101, which is in clinical development, and will require the effective execution of the Company’s business plan, significant capital resources, and a significant clinical development effort.

NKore currently has no products on the market. The Company’s most advanced product candidate, NK101, is starting human clinical use in Mexico to collect preliminary safety and efficacy data prior to filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA). NKore’s business plan depends almost entirely on the successful preclinical and clinical development, regulatory approval, and commercialization of NK101, and substantial clinical development and regulatory approval efforts will be required before the Company is permitted to commence commercialization, if ever. The clinical trials, manufacturing, marketing of NK101 will be subject to extensive and rigorous review and regulation by numerous government authorities in the U.S., the European Union (EU), and other jurisdictions where the Company intends to perform studies and, if approved, market its product candidates.

Before obtaining regulatory approvals for the commercial sale of any product candidate, NKore must demonstrate through preclinical testing and clinical trials that its product candidates are safe and effective for use in each target indication, and potentially in specific patient populations. Of the substantial number of drugs in development for approval in the U.S. and the EU, only a small percentage successfully complete the FDA regulatory approval process. Accordingly, even if NKore can obtain the requisite financing to continue to fund its research, development, and

clinical programs, it cannot guarantee that any of its product candidates will be successfully developed or commercialized.

Because the results of efficacy and preclinical studies are not necessarily predictive of future results, NK101 may not have favorable results in the Company's planned clinical trials.

Any positive results from efficacy in preclinical testing of NK101 may not necessarily be predictive of the results from the Company's current and planned clinical trials. In addition, NKore's interpretation of clinical data or its conclusions based on the preclinical *in vitro* and *in vivo* models may prove inaccurate. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development, and NKore cannot be certain that it will not face similar setbacks. Moreover, preclinical data can be susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies nonetheless failed to obtain FDA approval. If NKore fails to produce positive results in its planned clinical trials, the development timeline and regulatory approval and commercialization prospects for NK101, and, correspondingly, the Company's business and financial prospects, would be materially adversely affected.

Failures or delays in the Company's planned clinical trials of NK101 could result in increased costs and could delay, prevent, or limit NKore's ability to generate revenue and continue its business.

Successful completion of clinical trials is a prerequisite to submitting a Biologics License Application (BLA) to the FDA, which is required for commercialization. Clinical trials are expensive, difficult to design and implement, and are uncertain as to the outcome. A product candidate can unexpectedly fail at any stage of clinical development. The historic failure rate for product candidates is high due to factors, including scientific feasibility, findings related to safety and efficacy, changing regulatory standards, and standards of medical care and other variables. NKore does not know whether its clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons. If the Company's clinical trials fail or are delayed, its development costs may increase, the approval process could be delayed and NKore's ability to commercialize its product candidates could be materially harmed, which could have a material adverse effect on its business, financial condition, or results of operations.

NKore has initiated a human clinical use for NK101 outside the U.S., and the Company may choose to conduct additional clinical trials for NK101 outside the U.S., where the FDA may not accept data from such trials.

NKore has initiated human clinical use of NK101 in Cancun, Mexico, and it may choose to conduct additional clinical activities for NK101 in countries outside the U.S, subject to applicable regulatory requirements in any such country. The Company plans to include relevant clinical safety data collected in connection with the treatment of patients in Mexico in its IND application for NK101 to be filed with the FDA. Although the FDA may accept data from clinical use conducted outside the U.S., acceptance of such data is subject to certain conditions. For example, the clinical use must be conducted in accordance with Good Clinical Practice (GCP) requirements and the FDA must be able to validate the data through an onsite inspection if it deems such inspection necessary. There can be no assurance the FDA will accept data from clinical use conducted outside of the U.S., particularly where such data is not collected as part of a formal clinical trial. If the FDA does not accept any such data, it could result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of the development plan.

Even if NKore can commercialize NK101, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm the Company's business.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of the Company's product candidates, if approved, will depend substantially on the extent to which the costs of these product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers, and other third-party payors. If reimbursement is not available, or is available only to limited levels, the Company may not be able to successfully commercialize NK101.

Even if coverage is provided, the approved reimbursement amount may not be high enough to allow NKore to establish or maintain pricing sufficient to realize a sufficient return on its investment.

The Company's product candidates, if approved, may be unable to achieve broad market acceptance and, consequently, limit its ability to generate revenue and profits from new products.

Even when product development is successful and regulatory approval has been obtained, NKore's ability to generate significant revenue and profits depends on the acceptance of its products by physicians and patients. The market acceptance of any product depends on a number of factors, including but not limited to awareness of a product's availability and benefits, the indication statement and warnings approved by regulatory authorities in the product label, continued demonstration of efficacy and safety in commercial use, perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of the Company's drugs, physicians' willingness to prescribe the product, reimbursement from third-party payors, such as government healthcare systems and insurance companies, the price of the product, pharmacological benefit and cost-effectiveness of the products relative to competing products; competition, and the effectiveness of marketing and distribution efforts. Any factors preventing or limiting the market acceptance of the Company's product candidates could have a material adverse effect on its business, results of operations, and financial condition.

Any inability to attract and retain qualified key management and technical personnel would impair the Company's ability to implement its business plan.

NKore's success depends on the continued service of key management and other specialized personnel. The loss of one or more members of its management team or other key employees or consultants could delay the research and development programs and materially harm its business, financial condition, results of operations and prospects. NKore does not maintain key person life insurance policies for any members of its management team. The Company future success and growth will depend in large part on its continued ability to attract and retain other highly qualified scientific, technical and management personnel and consultants, as well as personnel and consultants with expertise in clinical testing, manufacturing, governmental regulation, and commercialization. NKore faces competition for personnel and consultants from other companies, universities, public and private research institutions, government entities, and other organizations.

NKore faces substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than it does.

The development and commercialization of drugs is highly competitive. NKore competes with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed at universities and other research institutions. The Company's competitors have developed, are developing, or will develop product candidates and processes competitive with NKore's product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. If NK101 is approved for the indications it is currently pursuing, it will compete with a range of therapeutic treatments that are either in development or currently marketed, as further described in the competition section (pages 50-51).

More established companies may have a competitive advantage over the Company due to their greater size, cash flows, and institutional experience. Compared to NKore, many of its competitors may have significantly greater financial, technical, and human resources. As a result of these factors, competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before NKore is able to, which may limit its ability to develop or commercialize product candidates. Competitors may also develop drugs that are safer, more effective, more widely used, and less expensive, and may also be more successful than NKore in manufacturing and marketing their products. These advantages could materially impact the Company's ability to develop and, if approved, commercialize NK101 successfully.

Product liability lawsuits against NKore could cause it to incur substantial liabilities.

The Company's use of NK101 in clinical trials and the sale of NK101, if approved, exposes NKore to the risk of product liability claims. Product liability claims might be brought against the Company by patients, healthcare providers, or others selling or otherwise encountering NK101. 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, including because of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If NKore becomes subject to product liability claims and cannot successfully defend itself against them, it could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things, withdrawal of patients from the Company's expected clinical trials; decreased demand for NK101 following marketing approval, if obtained; and damage to the Company's reputation and exposure to adverse publicity.

Business or economic disruptions or global health concerns could seriously harm the Company's development efforts and increase its costs and expenses.

Broad-based business or economic disruptions could adversely affect NKore's ongoing or planned research and development. For example, the COVID-19 outbreak has resulted in extended closures, disruptions of businesses, services, or facilities, and lead to workforce instability in the affected areas, which may impact NKore or its suppliers' operations. Global epidemics and pandemics, such as COVID-19, could also negatively affect the hospitals and clinical sites in which NKore conducts any of its clinical trials, which could have a material adverse effect on its business and results of operation, and financial condition.

RISKS RELATED TO NKORE'S INTELLECTUAL PROPERTY

If NKore is unable to protect its intellectual property rights or if its intellectual property rights are inadequate for its technology and product candidates, the Company's competitive position could be harmed.

NKore's commercial success depends in large part on its ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to the Company's proprietary technology and products. NKore relies on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. The Company seeks to protect its proprietary position by filing, securing, and prosecuting patent applications in the U.S. and abroad related to its technologies and products that are important to the business.

The patent positions of biotechnology and pharmaceutical companies are highly uncertain, involve complex legal and factual questions, and have in recent years been the subject of litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of NKore's patents are highly uncertain. The steps the Company has taken to protect its proprietary rights may not be adequate to preclude misappropriation of proprietary information or infringement of its intellectual property rights, both inside and outside the U.S. NKore does not know whether the pending patent applications for any of its product candidates will result in the issuance of any patents that protect its technology or products, or if any of its issued patents will effectively prevent others from commercializing competitive technologies and products. If NKore is unable to obtain and maintain patent protection for its technology and products, or if the scope of the patent protection obtained is not sufficient, competitors could develop and commercialize technology and similar or superior products, and the Company's ability to successfully commercialize its technology and products may be adversely affected.

Protecting against the unauthorized use of NKore's patented technology, trademarks, and other intellectual property rights is expensive, difficult, and may in some cases not be possible. It may be difficult or impossible to detect third-party infringement or misappropriation of the Company's intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

NKore may become subject to claims by third parties asserting that it or its employees have misappropriated their intellectual property or claiming ownership of what the Company regards as its own intellectual property.

NKore's commercial success depends upon its ability to develop, manufacture, market, and sell its product candidates, and to use its related proprietary technologies without violating the intellectual property rights of others. The Company may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement or post grant invalidation claims against NKore based on existing patents or patents that may be granted in the future. If the Company is found to infringe a third party's intellectual property rights, it could be required to obtain a license from such third party to continue commercializing its product candidates. However, NKore may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, the Company could be forced, including by court order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, NKore could be found liable for monetary damages. A finding of infringement could prevent the Company from commercializing its product candidates or force it to cease its business operations, which could materially harm its business. Any claims by third parties that NKore has misappropriated their confidential information or trade secrets could have a similar negative impact on its business.

NKore may become involved in lawsuits to protect or enforce its intellectual property, which could be expensive, time consuming, and unsuccessful and have a material adverse effect on the success of its business.

Competitors may infringe on NKore's patents or misappropriate or otherwise violate its intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend the Company's intellectual property rights, to protect its trade secrets, or to determine the validity and scope of its own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against NKore to challenge the validity or scope of intellectual property rights it owns. These proceedings can be expensive and time-consuming. Many of the Company's current and potential competitors can dedicate greater resources to defend their intellectual property rights than it can. Accordingly, despite NKore's efforts, it may not be able to prevent third parties from infringing upon or misappropriating its intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm its business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by the Company is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that NKore's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of NKore's patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that the Company's confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments.

RISKS RELATED TO THE COMPANY

NKore has a limited operating history on which to judge its business prospects and management.

The Company was formed in 2020. Accordingly, it has a limited operating history upon which to base an evaluation of its business and prospects. Operating results for future periods are subject to uncertainties and NKore cannot guarantee that the Company will achieve or sustain profitability. The Company's prospects must be considered considering the risks encountered by companies in the early stage of development, particularly companies in new and rapidly evolving markets. Future operating results will depend upon factors, including the Company's success in attracting and retaining motivated and qualified personnel, its ability to establish short term credit lines or obtain financing from other sources, its ability to develop and market new products, control costs, and general economic conditions. NKore cannot guarantee that the Company will successfully address any of these risks.

The Company will need (but may be unable to obtain) additional funding on satisfactory terms, which could impose burdensome financial restrictions on its business.

NKore is a company focused on NK101's clinical development and has not generated any product revenues to date. The Company will need to continue to seek capital from time to time to continue the development and potential commercialization of its product candidates. Future financing may not be available on a timely basis, in sufficient amounts, or on terms acceptable to the Company, if at all. If the Company cannot raise adequate funds to satisfy its capital requirements, NKore will have to delay, scale-back, or eliminate its development activities, and may be unable to complete planned nonclinical studies and clinical trials or obtain approval of its product candidates from the FDA. Any of these actions may harm the Company's business, financial condition, and results of operations.

RISKS RELATED TO NKORE'S DEPENDENCE ON THIRD PARTIES

NKore currently relies on third parties—CROs, clinical data management organizations, and consultants—to design and/or conduct its research, preclinical studies, and current and expected clinical trials. If these third parties do not successfully perform their contractual duties or meet expected deadlines, the Company may not be able to obtain regulatory approval for or commercialize its product candidates. NKore and its CROs are required to comply with various regulations which are enforced by the FDA and other regulatory agencies, including GMP, GCP and Good Laboratory Practices (GLP), to ensure that the health, safety, and rights of patients are protected in preclinical studies, clinical development, and clinical trials, and that trial data integrity is assured. Failure to comply with these regulations may require NKore to repeat its clinical trials, which would delay the regulatory approval process.

NKore's reliance on third parties that it does not control does not relieve it of these responsibilities and requirements. If the Company or any of its CROs fail to comply with applicable requirements, the clinical data generated in the clinical trials may be deemed unreliable and the FDA may require NKore to perform additional clinical trials before approving its marketing applications.

In addition, the use of third-party service providers requires the Company to disclose its proprietary information to these parties, which could increase the risk that this information will be misappropriated. Though NKore carefully manages its relationships with its CROs, there can be no assurance that the Company will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition, and prospects.

NKore relies on third-party manufacturers and suppliers to produce preclinical and clinical supplies and intends to rely on third-party manufacturers for commercial supplies and final dosage forms for NK101, if approved.

The Company relies on third parties to supply the materials for (and manufacture) its research and development, and preclinical and clinical trials. NKore does not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that its supply of research and development, preclinical, and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Any replacement of the Company's contract manufacturing organizations (CMOs) could require significant effort and expertise because there may be a limited number of qualified manufacturers.

NKore expects to continue to rely on third-party manufacturers if it receives regulatory approval for any product candidate. To the extent that it has existing, or enters into future manufacturing arrangements with third parties, NKore will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If the Company is unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, it may not be able to develop and commercialize its product candidates successfully.

NKore's third-party manufacturers also may use hazardous materials, including radioactive compounds or chemicals and compounds that could be dangerous to human health and safety or the environment, and their operations may also produce hazardous waste products. In the event of contamination or injury, the Company's third-party manufacturers could be held liable for damages or be penalized with fines in an amount exceeding their resources, which could result in NKore's clinical trials or regulatory approvals being delayed or suspended.

Glossary

Allogeneic—Taken from different individuals of the same species. Also called allogenic.

Blood Brain Barrier—A physiological mechanism that alters the permeability of brain capillaries so that substances, such as certain drugs, are prevented from entering brain tissue, while other substances are allowed to enter freely.

Bone Marrow Aspirate—A procedure in which a small sample of the liquid part of the bone marrow is removed for pathologic analysis. Bone marrow aspiration is used in the diagnosis of conditions, including leukemia, multiple myeloma, and lymphoma, and is also used to determine the extent to which cancer cells have spread to the bones.

Bone Marrow-liver-thymus (BLT) Mice—A mouse model that more closely replicates the human immune system than standard mouse models, therefore providing a powerful tool to study human immunology and immunotherapy. The BLT-mice model was developed to provide an animal model that could, to the extent possible, mimic portions of a functioning human immune system to accurately model the human immune response to pathogens or therapies.

Cancer Stem Cells (CSC)—A subpopulation of tumor cells displaying self-renewal ability, and multi-lineage differentiation, contributing to tumor progression, recurrence, and metastasis. CSCs are more resistant to radiation and chemotherapeutic agents compared to other cancer cells and, therefore, survive conventional therapies, resulting in local and distant relapse of the disease and metastasis.

Chimeric Antigen Receptor T lymphocyte (CAR-T) Therapy—A type of immunotherapy that uses receptor proteins that have been engineered to give T-cells the new ability to target a specific antigen. These cells are genetically engineered (changed) in a laboratory so they can bind to cancer cells and kill them.

Chronic Lymphocytic Leukemia (CLL)—The most common form of leukemia in adults, in which the lymphocytes may look normal but are not fully mature and do not deal effectively with infection. The malignant cells are found in the blood and bone marrow, collect in and enlarge the lymph nodes, and may crowd out other blood cells in the bone marrow, resulting in a shortage of red blood cells (producing anemia) and platelets (producing easy bruising and bleeding).

Cytotoxic—A substance that has a toxic effect on certain cells. Cytotoxicity refers to the ability of a substance to kill cells.

Gamma Interferon (IFN- γ)—A cytokine that is critical for innate and adaptive immunity response. IFN- γ induces activation of macrophage to increase a variety of inflammatory mediators and increase tumoricidal properties and intracellular killing of pathogens.

Glioblastoma—A primary malignant tumor originating in the brain.

Immunotherapy—A treatment used to stimulate or restore the immune system's ability to combat disease and infection.

Interleukin-2 (IL-2)—A naturally produced protein of the immune system that stimulates the growth of specific types of white blood cells.

Investigational New Drug (IND)—Refers to the Food and Drug Administration's (FDA) program by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. The FDA reviews the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Lymphocytes—A type of white blood cell in the immune system of most vertebrates. Lymphocytes include T-cells, B-cells, and innate lymphoid cells, of which natural killer cells are an important subtype. They are the main type of cell found in lymph, which prompted the name “lymphocyte.” Lymphocytes make up between 18% and 42% of circulating white blood cells.

MHC class I—A diverse set of cell surface receptors expressed on all nucleated cells in the body, as well as platelets. MHC class I receptors play a key role in alerting the immune system to virally infected cells.

Natural Killer (NK) cells—A type of white blood cells (lymphocytes) which are part of the innate immune system and are best known for killing virally infected cells and detecting and controlling early signs of cancer. NK cells were first noticed for their ability to kill tumor cells without any priming or prior activation (in contrast to cytotoxic T-cells, which need priming by antigen presenting cells). Additionally, NK cells secrete cytokines such as IFN- γ and TNF α , which act on other immune cells to enhance the immune response.

Non-Hodgkin’s Lymphoma—Malignant tumors of the lymphatic system consisting of subtypes of lymphatic cancer.

Optic Pathway Glioma—A slow-growing brain tumor that arises in or around the optic nerve, which connects the eye to the brain. As the tumor progresses, it presses on the optic nerve, causing a child’s vision to worsen. Because the optic system is located near the hormone center of the brain, these tumors can affect the body’s endocrine functions, such as hormone production, salt and water balance, appetite, and sleep.

T-cells—White blood cells that are important to the immune system and are at the core of adaptive immunity, which is the system that tailors the body’s immune response to specific pathogens.

Tumor Microenvironment (TME)—A complex ecosystem surrounding a tumor, composed of cancer cells, stromal tissue and the extracellular matrix.

Tumor Necrosis Factor Alpha (TNF-a)—A subgroup of molecules capable of initiating signaling cascades that increase cell proliferation, differentiation, and apoptosis.



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