Nami Therapeutics Corporation. Improving Patient Outcomes Using Nanotherapies

Xiuling Lu, PhD, CEO | lu@namitherapeutics.com | www.namitherapeutics.com

Company Overview

Nami Therapeutics Corporation (Nami) is a specialty pre-clinical nanotechnology platform company developing cutting edge precision cancer nanotherapies. Nami was established in 2018 and is focused on developing specifically designed nanocarrier platforms for targeted delivery of radiotherapies and chemotherapeutic agents to tumor cells. Nami nanotechnology can improve the efficacy and reduce toxicities of therapeutic radiopharmaceuticals and anti-cancer drugs across all tumor types. Current efforts at Nami are focused on two lead programs: 1) XLNT-1, radioisotope-loaded nanoparticles formulated for intraperitoneal delivery to treat peritoneal metastases, with a lead indication target of ovarian cancer; 2) XLNT-2, nanoparticles containing chemotherapeutic agents specifically designed to inhibit leukemic stem cells (LSC) in order to cut the root of treatment resistance and cancer recurrence in leukemias and lymphomas. Nami has exclusive rights to four patents associated with these technologies having allowance or are pending in the US, EU, JP, CN, and AUS.

Market and Commercialization Strategy

The global market for cancer therapies based on nanotechnology is expected to reach $55.4 billion in the United States with a compound annual growth rate (CAGR) of 14.9% in 2024. The ovarian cancer market was valued at $1.8 billion in 2018 across the seven major markets, and it is expected to grow to $6.7 billion in the following 10 years with a CAGR of 14.4%. The unmet needs in ovarian cancer are substantial as the 5-year survival rate is just 28%. XLNT-1 will be developed as a treatment for women with metastatic relapse or resistant ovarian cancer. Ultimately, XLNT-1 will be expanded and studied for the treatment of pancreatic and colorectal cancer patients with tumors that have spread to the abdomen. With respect to XLNT-2, the global leukemia therapeutics market increased from $7B in 2012 to $12B in 2017. The cancer stem cell (CSC) and LSC therapeutics markets are expected to exceed $1.9B and $600M, respectively, by 2022. XLNT-2 will be used as the frontline treatment in combination with standard chemotherapy to treat adult acute lymphocytic leukemia or acute myeloid Leukemia.

Technical & Competitive Advantage

Nami's two platform technologies address the limited options for relapsed and/or resistant cancer patients and offer another chance for a cancer-free life. The platforms allow for development of multiple subsequent products and a rich product portfolio.

XLNT-1 Comprises a tumor microenvironment targeting strategy with highly tumor-specific internal radiation to treat peritoneal metastasis. In animal models, survival time nearly doubled, with limited off-target radiation exposure and low toxicity. The primary indication is ovarian cancer peritoneal metastasis, with expansion into all types of peritoneal metastases.

XLNT-2: These proprietary, biocompatible polymeric nanoparticles can be used to carry a variety of hydrophobic and hydrophilic molecules. The anti-cancer drug doxorubicin, loaded into nanoparticles (XLNT-2), was more effective than small molecule doxorubicin and commercial liposomal doxorubicin in inhibiting leukemic stem cells in animal models with improved safety profiles.

Regulatory Strategy & Intellectual Property

Nami holds exclusive license to a US patent and a pending patent to protect XLNT-1. The product will be a radiopharmaceutical based on a recent pre-request for designation from FDA and will be pursued for fast-track approval. Nami also has exclusive rights to three pending or issued patents for XLNT-2. The drug-loaded nanoparticles will be designated as a new drug.

Key Milestones

Description	Date/Year
Completion of additional pre-clinical efficacy study	Q2, 2022
Completion of pre-IND application	Q3 2022
Completion of GMP preparation of nanomaterials and GLP toxicity study for XLNT-1	Q4 2022
Completion of IDE documentation preparation and submission	Q3 2023

Capitalization History

The technologies have been supported by around $1.6 M of research grants from NIH and American Cancer Society, including a recent STTR Phase I grant to Nami. Currently a SBIR Phase II grant with a total funding of $2M is pending.

Use of Proceeds

Seeking $5M in convertible debt to further CMC, manufacturing & operating costs through 2023 and targeting a Series A funding of ~$20M in late 2022 in order to move one of the two programs to clinical trials.

Key Team Members

Xiuling Lu, Ph.D., CEO, co-founder and key technology inventor, has over 16 years of experience working in materials science, drug formulation, and nanotechnology. **Michael Jay, Ph.D., Chief Scientific Officer** brings over 40 years of experience in drug development, pharmaceutical formulation, and imaging agents to Nami. He was the director of an FDA-registered cGMP manufacturing facility and is founder of five different companies, one of which is currently moving a product to clinical trials. **Ruobing Xia, M.B.A., Chief Commercial Officer** has over 20 years of experience in big pharma and repeated success leading product development projects at Eli Lilly and Boehringer Ingelheim and has managed hundreds of millions of dollars in product launches and promotions. **David Worthen, Ph.D., J.D., Head of R&D** has served for over 20 years as a senior scientist, project manager, group leader, and principal investigator in the pharmaceutical and consumer products areas in large industry, start-ups, contract research organizations, and academia. **Jeffrey C. Miller, M.B.A., Advisory Board Director** is COO at Catalytic Life Sciences, and has >25 years of experience in the bio/pharmaceutical industry with large, mid-size, and small companies across many disciplines.