



RAADYSAN BIOTECH, INC.



***DEVELOPING FIRST-IN CLASS THERAPIES
FOR TRIPLE NEGATIVE BREAST CANCER***



[Biotechnology Awards 2024](#)

EXECUTIVE SUMMARY

COMPANY DESCRIPTION

Background: Raadysan Biotech, Inc. ("The Company"), an award-winning clinical stage biotechnology company, is developing first-in-class therapies for Triple Negative Breast Cancer (TNBC). Their lead drug candidate inhibits TNBC tumor growth rate by 61% (monotherapy) in female mice, with complete tumor regression in one animal. They believe that their unique therapy will be effective for the treatment of all subtypes and ethnic groups of TNBCs. They are targeting a global market of \$48 billion and intend to license these therapies to Pharma companies, following Phase 1a/b clinical trials. They are also developing Companion Diagnostics for detection of TNBC.

Inventions:

- ❖ **Molecular target:** *The Company has identified a novel molecular target for Breast Cancer that:*
 - Is over-expressed in TNBC and other breast cancer cells and its inhibition selectively kills breast cancer cells.
 - Is directly involved in all stages of cell proliferation, including DNA replication, Mitosis & Cytokinesis.
 - Is Endocrine and growth receptor independent, unlike current therapies.
 - Can be used as a non-invasive diagnostic tool for acute and chronic myeloid leukemia.
 - Can function as a biomarker for the progression of cancer.

Notably, there are no therapies currently available in the market for the treatment of TNBC that targets the core DNA replication machinery.

- ❖ **Lead Drug Candidate:** Small Molecule Inhibitor against the novel molecular target
- **In vitro data in mesenchymal/metastatic TNBC cells (monotherapy):**
 - Inhibits the TNBC cell viability by 95%.
 - Down-regulates expression of the novel target protein by 47% in 24 hours, in vitro.
- **In vivo data in female mice with mesenchymal/metastatic TNBC cell xenograft (monotherapy):**
 - Inhibits TNBC tumor growth rate by 61%.
 - **Complete Regression in one animal**
 - Very few molecular target positive nuclei in treated versus untreated TNBC tumors
 - Fewer Ki-67 positive nuclei in treated versus untreated TNBC tumors
 - No loss in body weight indicating no toxic effects of the drug treatment on animals

PCT filed for: Small Molecule Inhibitor - Compounds and Methods
National Stage Filing – Completed for the US and Europe

The Company anticipates that they will be ready for IND filing by ~ 2028, followed by Phase 1 a/b Clinical trials by ~ 2029.

- ❖ **Companion Diagnostics:**
 - Companion IVD kits for breast cancer
 - 2 US patents

MARKET ANALYSIS

Growth: According to WHO, there were 2.8 million new cases of breast cancer, diagnosed worldwide, in 2020. Mordor Intelligence estimates the global cancer therapy market to be valued at \$220 billion in 2024, witnessing a CAGR of 8.37% and Global Market Insights projects the breast cancer therapy market to hit \$48 billion by 2029.

Competition: The major players in the targeted cancer therapy market includes traditional pharmaceutical companies such as Pfizer, Novartis, Roche/Genentech, Merck, Bristol-Myers Squibb, Amgen, H      , AstraZeneca, etc. However, the Company is confident that they will be able to secure business relationships with some of these competitors and look to them to be future licensees for the Company.

Unmet Medical Need: TNBC is the most aggressive type of breast cancer with high prevalence rates (15-20%), poor survival and high recurrence rates. Complex heterogeneity (6 subtypes) and ethnic disparity, associated with it, further complicates its treatment options, restricting it to radiation, chemotherapy, and surgery. Although newer drugs, such as combination of chemotherapy + immune-checkpoint inhibitors and/or DNA repair protein inhibitors, and more recently anti-Trop-2 monoclonal antibody + topoisomerase I inhibitor, have been tried for the treatment of TNBC, they offer incremental improvement in progression free survival by only 2.5-6 months. Many oncologists have voiced their limitations and frustration for lack of tools to treat this deadly disease and hope that new drugs and newer approaches, will equip them with options that will offer hope to the TNBC patients and improve survival rates. The sizable TNBC patient population, makes it imperative to expedite the development of effective targeted therapies for these patients. Therefore, a radically different approach; one that identifies molecular targets that are receptor independent and directly involved in cell proliferation, is crucial for the treatment of TNBC.

Value Proposition: The Company's lead drug candidate will offer the following benefits:

- ❖ Identified a novel molecular target.
- ❖ Revolutionary therapies that directly target core DNA replication machinery.
- ❖ Non-receptor-based therapy, hence, will work for all subtypes of breast cancer.
- ❖ Selectively targets only cancer cells.
- ❖ Inhibits TNBC cell viability (95%, in vitro) by necroptosis.
- ❖ **Inhibits TNBC tumor growth rate in female mice by 61% (monotherapy).**
- ❖ **Complete Regression in one animal.**
- ❖ May be effective treatment for chemotherapy induced apoptotic resistant cancer cells
- ❖ May be effective treatment for BRCA1-mutated TNBC.
- ❖ Huge market potential of \$ 48.0 billion.

Strategic Partners: The Company will target major national and international therapeutic, biotech, and pharmaceutical companies with existing anti-cancer drug portfolios.

COMPANY FINANCIALS

Capital Raised to Date: \$845,000 (Non-Dilutive)

Capital Requirements and Major Milestones to be achieved: The Company seeks to raise \$32.0 million in tranche financing:

- Seed: \$2.0 million – In vivo studies in female mice implanted with patient-derived xenografts of TNBC ~ 2026
- Series A: \$15.0 million – In vivo Efficacy testing/IND filing ~ 2027-28
- Series B: \$15.0 million - Phase 1a/b Clinical Trials ~ 2029

Use of Proceeds: Seed funding will be utilized for:

- R & D expenses - As mentioned above
- G & A expenses - IP protection and hiring personnel.

Exit Strategy: The Company intends to complete R & D of their lead drug candidate for the treatment of TNBC, followed by IND filing and Phase 1 a/b Trials. The Company's exit strategy would be either licensing, an outright acquisition, or an IPO, which would be dependent on opportunities and market conditions presented at that time.

TEAM

The Company is led by exceptional scientists whose visionary outlook has been instrumental in several innovative discoveries reflected in our portfolio. We have congregated a team of outstanding clinicians, management team and advisors with collective experience over 100 years.

- **Rakhee Gupte, MS, PhD, CEO & President:** has over 25 years of academic and pharmaceutical experience in drug development, diagnostics, manufacturing, and quality assurance. She has discovered unique molecular targets and developed RNAi and small molecule anti-breast cancer therapies. She received her MS Microbiology & Immunology from Bombay, India; and worked as a Senior Scientific Officer in Neo-Pharma, Bombay, India. She received her Ph.D. in Biochemistry & Molecular Biology from New York Medical College, Valhalla, NY. She was an Assistant Professor in the department of Biochemistry & Molecular Biology, University of South Alabama, Mobile, AL. Currently, she is appointed as a Visiting Professor in the Department of Pharmacology, New York Medical College, Valhalla, NY. She holds 5 US patents and 1 filed PCT and has authored/co-authored 23 publications. She is a Co-I on 2 NIH grants.
- **Steven Taylor, BSc, PhD, Chief Scientific Officer:** has 22 years of experience in all aspects of drug discovery and development, including structure-based drug design, HTS screens, and fast follower approaches, GMP manufacture, quality, formulation, analytical chemistry, and regulatory development. He received his bachelor's degree and PhD in Chemistry from the University of Sheffield, UK. Dr Taylor served as the Group Leader, at Evotec; and as VP Chemistry in Midatech Pharma. Dr Taylor has authored/co-authored 15 patent applications and 9 publications.
- **Roderike Pohl, PhD, Vice President-Research:** has over 20 years of pharmaceutical experience in the fields of pharmaceuticals, biopharmaceuticals, pharmacokinetics, pharmacodynamics, pre-formulation, formulation, analytical chemistry, and preclinical animal studies. She received her Ph.D. in Pharmaceutics from the University of Connecticut, Storrs, CT, and was the co-founder and Vice President of Research at Biodel Inc. She previously worked for Mannkind Corp. as Vice President of Preclinical Research, and Pharmaceutical Discovery Corp. as Director of Biopharmaceuticals and Preclinical Research.
- **Dr. Linda Vahdat, MD, MBA, Medical Advisor:** She received her MD from Mount Sinai School of Medicine and completed her fellowship in hematology and oncology at Memorial Sloan Kettering. She is the Deputy Cancer Center Director, Section Chief of Medical Oncology and Interim Chief of Hematology at Norris Cotton Cancer Center, NH, and is also the Milham Professor and Professor of Medicine at Dartmouth's Geisel School of Medicine. She has more than 20 years of experience in caring for patients with triple negative breast cancer and metastatic breast cancer. She has received many awards, including Physician of the Year and recognition as a Top Doctor by Castle Connolly multiple times throughout her career.
- **Nicholas Landekic, MA, MBA, Corporate Development Advisor:** has over 30 years of pharma experience in development of novel therapeutic drugs, marketing, finance, and corporate development. He received his MA in Biology from Indiana University and MBA in Finance/Marketing from State University of New York in Albany. He is a serial entrepreneur and founder of Karunix, Inc., and PolyMedix, Inc., with extensive experience in fund raising including 25 public and private financings.
- **Paul Mieyal, PhD, CFA, Strategic Advisor:** has over 20 years of experience investing in healthcare. He received his Ph.D. in pharmacology from New York Medical College and is a Chartered Financial Analyst. He was the Vice President and the Director of Life Sciences Investments of Wexford Capital. Currently he is the Managing Director at Outcome Capital.