GUIDELINES – PLEASE READ FIRST

- **Avoid confidential information** - this is a NON-CONFIDENTIAL deck that will be shared with industry experts
- **Keep it simple and direct** - successful applications demonstrate concisely how funds impact commercialization
- **Use graphics, charts, and tables** - examples are provided in the following slides
- **Business professional audience** - write for business professionals with high-level understanding of the field
- **You do not need to fulfill every bullet** – answer what you can to the best of your ability, finalists pitch decks will be honed further

PROJECT TITLE / TECHNOLOGY NAME

[Optional: Compelling tagline about the innovation]

Principal Investigator Name & Department

Date

<u>Funding for the project to date:</u>
$XXX F32
$XXX R01

EXECUTIVE SUMMARY / THE OPPORTUNITY

- Brief statement of the unmet need or problem
- Your proposed solution in one sentence
- Target market/customer
- Funding request amount
- Key use of funds (high-level)

TEAM

- Please include who you are and any key members who are working with you
- If you are developing a therapeutic, for example, are you an expert in the indication? If not, are you collaborating closely with an expert?
- If you are developing software, are you writing the code or are you working with an engineer?

THE PROBLEM / MARKET NEED

- Clear articulation of the significant unmet need
- Who experiences this problem? (specific customer/end-user)
- Current solutions and their limitations
- Market size estimate (TAM/SAM/SOM if available)
- Why this matters commercially

THE SOLUTION / TECHNOLOGY DESCRIPTION

- How your technology works (simple, clear explanation)
- What makes it unique/novel vs. existing approaches
- Key advantages and differentiation
- Why it's likely to succeed (preliminary data/proof points)

TECHNOLOGY STATUS, PRELIMINARY DATA, and IP

- Current stage of development
- Studies completed to date (link any publications)
- Key results/data showing feasibility
- Validation metrics achieved
- What has been de-risked so far

<u>On the IP – a footnote on</u>

- Patent filing status (filed, pending, issued)
- Type of protection (composition of matter, method, etc.)
- Strength of IP position
- [Note: Keep this non-confidential - no detailed claims]

COMPETITIVE LANDSCAPE

- Current alternatives (competitive products/approaches)
- Comparison table/matrix showing key features
- Your competitive advantages
- Barriers to entry for competitors
- Why customers would switch to your solution

COMMERCIALIZATION PATHWAY

- Where you are today (Likely proof-of-concept – which is OK)
- Major milestones ahead (Prototype, Testing, Approval Studies, Commercialization)
- Regulatory milestones (if applicable)
- IP milestones
- Estimated timeframes and costs for each phase

PROJECT PLAN & MILESTONES

- Specific objectives for this funding period (~3-4 months, up to 9 months)
- Quantifiable milestones
- Success metrics/validation criteria
- Key deliverables
- How these milestones advance commercialization

BUDGET & USE OF FUNDS

- Total funding request
- Budget breakdown by major categories
- How funds directly enable key milestones
- [Note: No indirect costs per JHTV guidelines]

RISK ASSESSMENT & MITIGATION

- Technology risks
- Market risks
- Regulatory risks (if applicable)
- Competition risks
- Mitigation strategies for each

LOS / CURRENT ENGAGEMENTS

- If you have any industry partners who would be willing to submit a LOS please let us know here

Example Deck Below

Please note this is illustrative and not meant to be directly copied but instead used as inspiration and orientation to what a successful deck might look like

PSMA-Targeted Nanoparticle Platform for Prostate Cancer Therapy

Delivering precision medicine to prostate cancer patients through targeted nanotherapy

Principal Investigator Name & Department

Date

Funding for the project to date:
$XXX F31
$XXX R01
$XXX MII Technology Assessment Award

Executive Summary

OPPORTUNITY

- 240,000+ new prostate cancer cases annually in the U.S.
- Limited targeted delivery options lead to systemic toxicity
- Our PSMA-targeted nanoparticle platform enables precision drug delivery

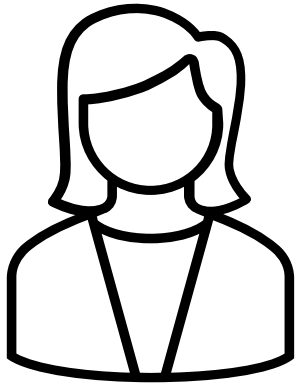
OUR SOLUTION

PEGylated nanoparticle system functionalized with potent PSMA inhibitor for selective prostate cancer cell targeting and drug delivery

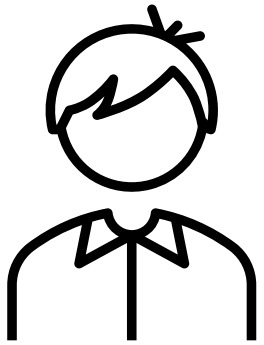
FUNDING REQUEST: $50,000 over 9 months

KEY USE OF FUNDS: In vivo efficacy studies and formulation optimization for IND-enabling studies

Team

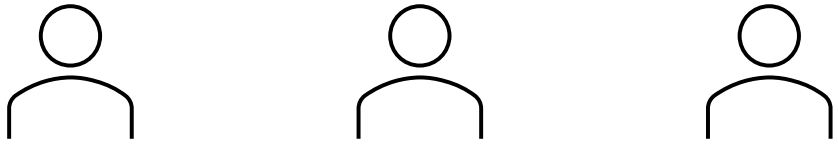


First Last, MD
Principal Investigator
20+ years as specialist in XXX



First Last, PhD
Post-Doctoral Fellow
Technical / Experimental Expert

First Last, MBA
Formerly at Biotech XYZ
>10 years experience selling XXX



Can include meaningful collaborators as well

Problem – Systemic Toxicity & Limited Targeting

THE CLINICAL CHALLENGE

- Prostate cancer: 2nd leading cause of cancer death in men
- 240,000+ new cases/year (U.S.) | ~1.4M globally
- Advanced disease requires chemotherapy with significant side effects

CURRENT LIMITATIONS

- Systemic chemotherapy affects healthy and cancer cells equally
- Dose-limiting toxicities reduce treatment efficacy
- Poor drug accumulation in tumor tissue
- Patient quality of life significantly impacted

TARGET PATIENT POPULATION

- ~60,000 men with metastatic castration-resistant prostate cancer (mCRPC)
- Patients requiring chemotherapy but unable to tolerate full doses
- Market: **$4.2B+ for advanced prostate cancer therapeutics**

Solution

HOW IT WORKS

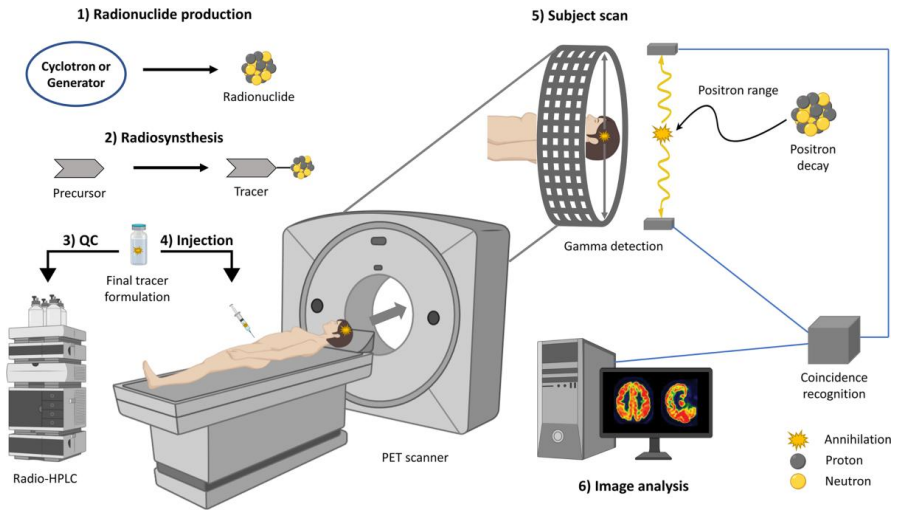
- Polymeric nanoparticle core loaded with chemotherapeutic
- PEGylated surface provides stealth circulation
- Selective binding to PSMA+ prostate cancer cells

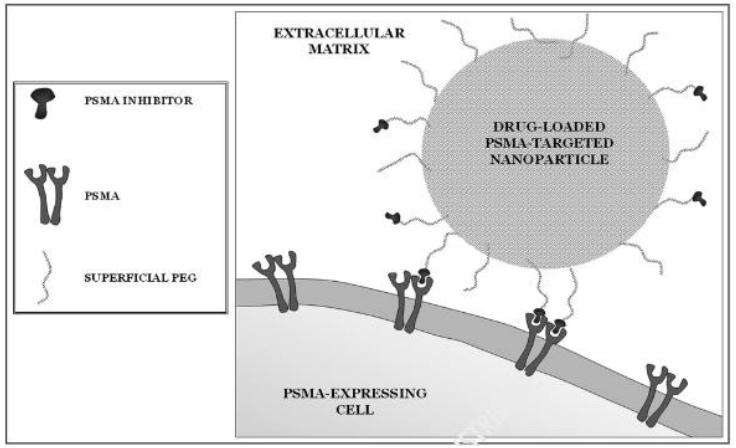
KEY INNOVATIONS

- **Versatile platform:** Can load various chemotherapeutics
- **High specificity:** PSMA overexpressed 100-1000x in prostate cancer vs. normal tissue
- **Reduced systemic toxicity:** Targeted delivery spares healthy tissue

WHY THIS WILL SUCCEED

- PSMA: validated, highly specific prostate cancer biomarker
- EPR effect: well-established for nanoparticle tumor accumulation
- Proof-of-concept: demonstrated specific binding and selective cytotoxicity in vitro





Technology Status, Preliminary Data, and IP

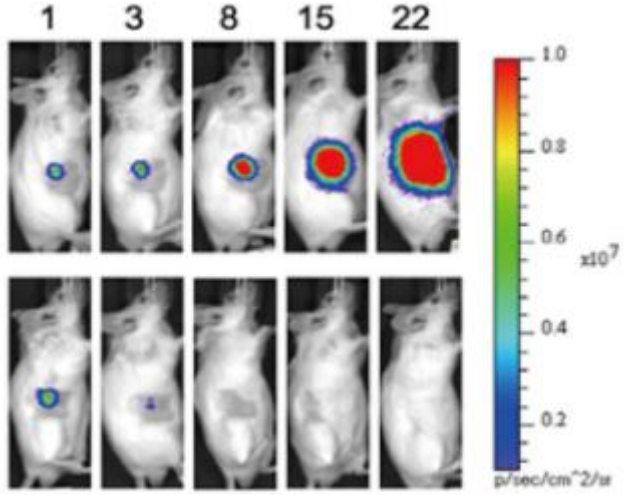
CURRENT STAGE: Proof-of-Concept (in vitro validation complete)

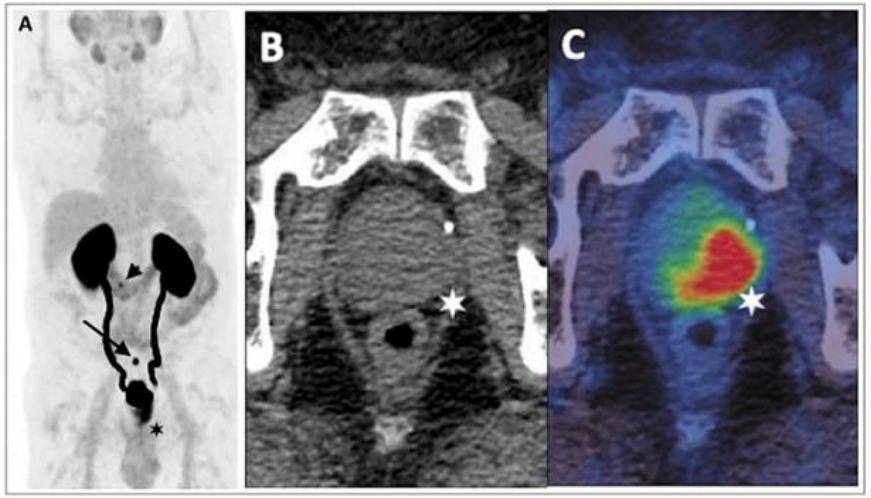
STUDIES COMPLETED (link to paper if possible):

- Nanoparticle synthesis and characterization
- PSMA-inhibitor conjugation and surface functionalization
- Drug loading optimization

KEY RESULTS (link to paper if possible):

- ✓ Successful synthesis of PSMA target nanoparticles
- ✓ Specific binding to PSMA+ cells
- ✓ **5-fold higher** cellular uptake in PSMA+ cells





PATENT STATUS:
U.S. Patent Granted: [XX/XX] - Composition of Matter
Patent Application #: USXXXXXXXX

Competitive Advantage

KEY COMPETITIVE ADVANTAGES:

- **Cost-effective:** Small molecule targeting vs. expensive antibodies
- **Lower immunogenicity:** Synthetic polymers vs. biological antibodies
- **First-mover advantage:** Early-stage PSMA-targeted nanomedicine

Feature	OUR PLATFORM	Standard Chemo (Docetaxel)	Antibody-Drug Conjugates	Competitor NP (Generic)
PSMA Targeting	Yes (small molecule)	None	Yes (antibody)	None
Tumor Accumulation	**25-30%**	<5% of dose	10-15%	15-20%
Systemic Toxicity	**Low**	High	Moderate	Moderate
Drug Loading Capacity	**High (flexible)**	N/A	Limited (3-4 drugs)	Moderate
Manufacturing Cost	**Moderate**	Low	Very High	Moderate
Immune Response	**Very Low**	None	High (antibody)	Low
Versatility	**Platform (multiple drugs)**	Single drug	Single conjugate	Limited

Commercialization Pathway

WHERE WE ARE TODAY

- Proof-of-concept stage with compelling in vitro data
- Patent granted (Composition of Matter)

MILESTONES ENABLED BY THIS FUNDING ($50K)

- In vivo efficacy and biodistribution data package
- Optimized, reproducible formulation
- Lead drug cargo identified

Phase	Funding	Q1-Q2 Y1	Q3-Q4 Y1	Q1-Q2 Y2	Q3-Q4 Y2	Q1-Q2 Y3	Q3-Q4 Y3	Q1-Q4 Y4	Q1-Q4 Y5
JHTV Translational Funding	$50K								
IND-Enabling Studies	$500K-$1M								
IND Filing	$200K								
Phase I Clinical Trial	$2-5M								
Phase II Clinical Trial	$10-20M								

Project Plan & Milestones

Month	Milestone	Activities	Success Metrics	Budget
1-2	**Formulation Optimization**	• Scale-up synthesis • Drug loading optimization • Stability testing	• 3 batches, >95% reproducibility • Drug loading >10% • 6-month stability data	$8,000
3-4	**In Vivo Biodistribution**	• Mouse xenograft model • Radiolabeling studies • Tumor accumulation	• >2-fold tumor accumulation vs. control • PK parameters established	$15,000
5-6	**In Vivo Efficacy - Pilot**	• Therapeutic efficacy study • Dose-response testing • Toxicity assessment	• >50% tumor growth inhibition • Improved survival vs. free drug • No dose-limiting toxicity	$18,000
7-8	**Cargo Optimization**	• Test 2-3 alternative chemo agents • Compare efficacy profiles	• Identify lead candidate • IC90 at tolerable dose	$6,000
9	**Data Package & Strategy**	• Compile results • IND pathway consultation • Investor materials	• Complete data package • IND strategy defined • Licensing discussions initiated	$3,000

KEY DELIVERABLES:

- Optimized, reproducible nanoparticle formulation
- In vivo proof-of-concept data package
- Lead candidate drug cargo identified
- IND regulatory strategy
- Preliminary manufacturing scale-up plan

Budget & Use of Funds

BUDGET NOTES:

- All animal work through JHU animal facility
- No faculty salary (per JHTV guidelines)
- No indirect costs (per JHTV guidelines)
- Leveraging existing lab equipment and core facilities

This investment directly enables **in vivo validation** a necessary step for raising further funding

Category	Amount	Justification
Animal Studies	$25,000	• Xenograft model establishment ($8K) • Biodistribution studies - 30 mice ($9K) • Efficacy study - 40 mice ($8K)
Materials & Reagents	$12,000	• Polymer synthesis materials ($3K) • Chemotherapeutic drugs ($4K) • Radiolabeling reagents ($3K) • Cell culture & assay reagents ($2K)
Analytical Services	$8,000	• Particle characterization (DLS, TEM) ($3K) • Drug quantification (HPLC) ($2K) • PK analysis (LC-MS/MS) ($3K)
Regulatory Consulting	$3,000	• Pre-IND strategy consultation • CMC pathway planning
Other	$2,000	• Student/tech support hours • Publication costs

Risk assessment and Mitigation

Risk Category	Specific Risk	Likelihood	Impact	Mitigation Strategy
Technology	In vivo efficacy doesn't match in vitro results	Medium	High	Optimizing formulation parameters; testing multiple drug cargos; dose-response studies
Technology	Manufacturing scale-up challenges	Medium	Medium	Early engagement with CMO partners; process development during this funding period
Technology	Nanoparticle stability issues	Low	Medium	Extensive stability testing built into milestones; lyophilization development
Market	Competitor advances PSMA-targeted therapy first	Medium	Medium	Platform flexibility allows pivot to different payloads; combination therapy positioning
Market	Shift in prostate cancer treatment paradigm	Low	High	Versatile platform can target other PSMA+ cancers (renal, glioblastoma)
Regulatory	FDA requires extensive nanoparticle characterization	High	Medium	Proactive CMC development; early FDA engagement via pre-IND meeting
Regulatory	Clinical endpoint selection challenges	Medium	Medium	Collaborate with KOLs; design adaptive trial protocols
Competition	Large pharma enters PSMA-targeted delivery space	Medium	Medium	First-mover advantage; strong IP position; cost advantages vs. antibody approaches
Execution	Key personnel departure	Low	High	Cross-training team members; documenting all protocols

Industry Interest

Letter of Intent – [Company X Name]

- Leading oncology-focused pharmaceutical company
- Expressed interest in licensing pending in vivo data
- LOI available upon request