

# Empowering Immuno-Oncology Therapies By Stimulating the Immune System: **A Novel 1-2 Punch Against Cancer**

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CSE: SONA | OTCQB: SNANF

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Such forward-looking statements include, but are not limited to, statements regarding the benefits to accrue to Sona from the future development of Targeted Hyperthermia Therapy and the development of diagnostic devices.

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## Using Proprietary, Uniquely Biocompatible Nanotechnology for a More Effective <u>and</u> Gentler Cancer Therapy That Enables Immunology

#### Sona's Proprietary Technology

 Patented, biocompatible, proprietary gold nanorod manufacturing technology

#### Used to Develop:

#### Therapies

- Developing 'Targeted Hyperthermia Therapy' to eliminate tumors with minimal systemic toxicity
- Diagnostics
- Developer of novel lateral flow assay rapid tests for concussions and animal disease

# Which then would be licensed to commercialization partners

#### Sono

\* CTAB: Cetrimonium Bromide

#### Sona's Gold Nanorod Advantages

#### Uniquely Biocompatible:

- Sona surfactant uses no toxic CTAB \*
- Equally as effective at heat transfer as CTAB-based GNRs
- Potentially more suitable for use in the body: stable, inert and biocompatible

#### Functional:

- · Gold nanorods provide the most efficient thermal conversion
- Variety of lengths and widths to optimize surface area
- · Aspect ratio control permits tuning to specific wave lengths
- Long shelf life and stable surface properties

#### Validated :

- NCL was established by the FDA & NCI to accelerate the progress of nanomedicine by providing testing and characterization of nanoparticles.
  - Neither endotoxins nor microbial contamination were detected in seven rounds of NCL analysis



• NCL joined as part of Sona's team in its recent FDA 'Pre-sub' meeting

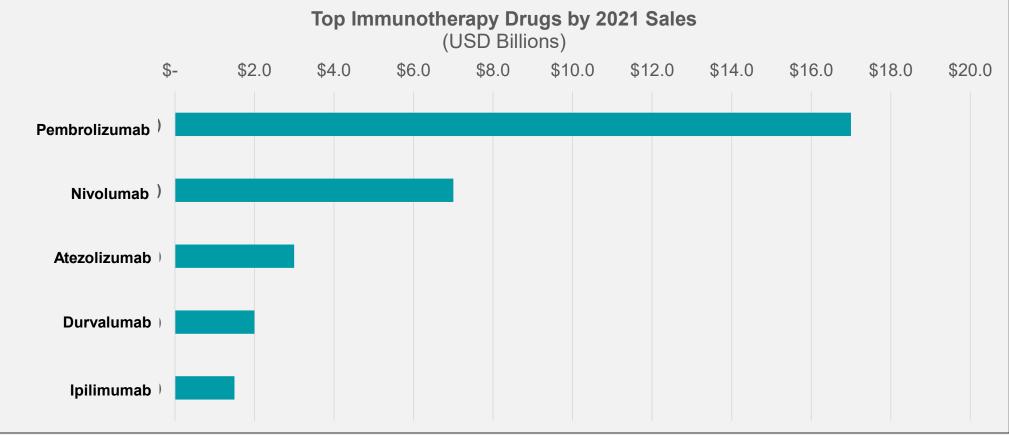
## Sona's Cancer Therapy Shrinks Tumors, And Is Prescribed With Current Immunotherapies, Making Those Drugs Work *Much* Better

### Sona's 'Targeted Hyperthermia Therapy' for Cancer

- 1. Tumor is injected with Sona's biocompatible gold nanorods
- 2. Sona's light energy device is applied to the tumor
- 3. Cancer cells are destroyed selectively, shrinking the tumor and triggering the release of *new antigens*
- 4. These new antigens enable immunotherapy to work much better, cleaning the job and possible even destroying distant, untreated tumors

## Sona's THT therapy could therefore bring value to the immunooncology industry

# \$31 Billion Was Spent On Immuno-Oncology ("IO") Drugs In The U.S. For Solid Cancers In 2021



Sources:

https://www.statista.com/statistics/1269401/revenues-of-keytruda/ https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-opdivo-1127420/

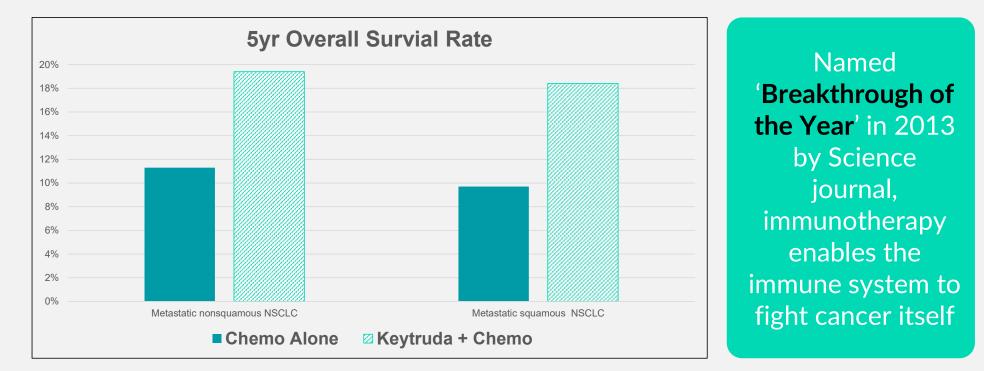
(manotech)

https://www.astrazeneca.com/content/dam/az/PDF/2021/full-year/Full-year-2021-results-announcement.pdf

https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-tecentrig-1127456/

https://www.precisionmedicineonline.com/business-news/bms-posts-strong-q4-precision-oncology-products-sales#:::text=Opdivo%20revenues%20in%202022%20were,from%20%242.03%20billion%20in%202022.

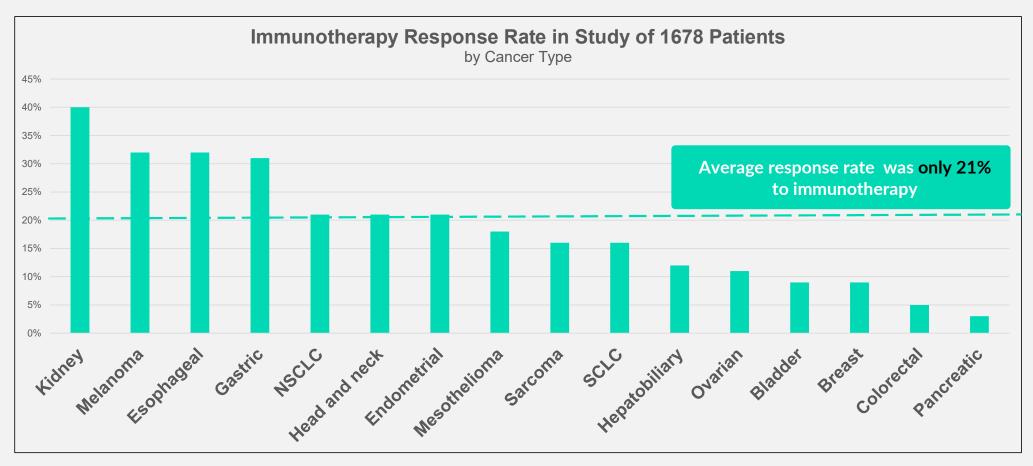
# IO Therapies Vastly Improve Survival Rates Vs. Chemo Alone



## In a study by Merck, their blockbuster IO product Keytruda increased five-year survival rates by ~81%

Sources: CA A Cancer J Clinicians, Volume: 73, Issue: 1, Pages: 17-48, First published: 12 January 2023, DOI: (10.3322/caac.21763) Response Rates to Anti–PD-1 Immunotherapy in Microsatellite-Stable Solid Tumors With 10 or More Mutations per Megabase Cristina Valero, MD, PhD,<sup>1</sup> et al

# But IO Therapy Response Rates Are Still Very Limited

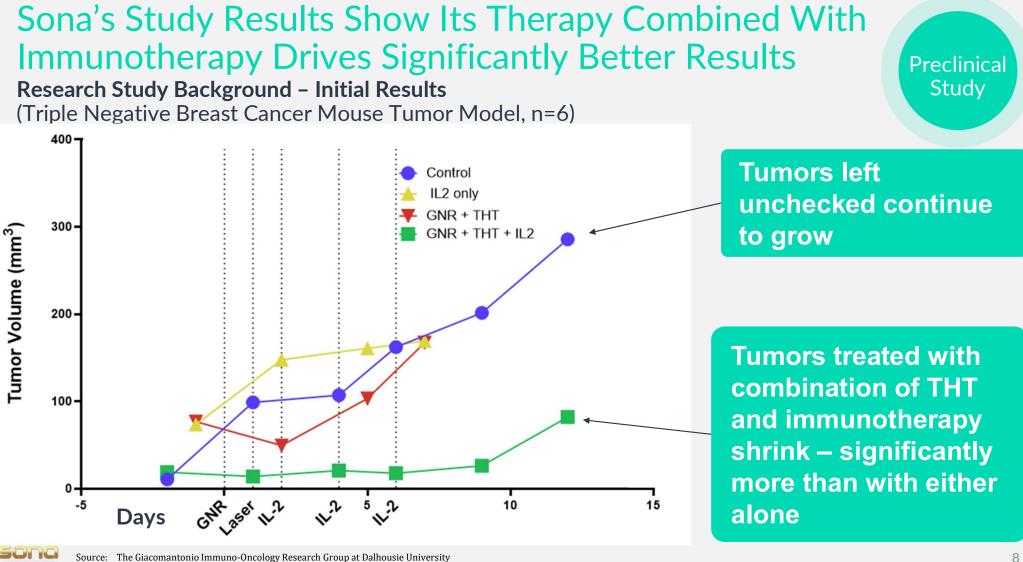




Note: Patients treated with anti-programmed cell death 1 or programmed cell death ligand-1 immunotherapy

Sources: CA A Cancer J Clinicians, Volume: 73, Issue: 1, Pages: 17-48, First published: 12 January 2023, DOI: (10.3322/caac.21763)

Response Rates to Anti-PD-1 Immunotherapy in Microsatellite-Stable Solid Tumors With 10 or More Mutations per Megabase Cristina Valero, MD, PhD,<sup>1</sup> et al



## The Main Reason IO Success On Its Own Can Be Constrained Is If Tumor Antigens Presented Are Too Weak To Elicit An Immune Response

### Sources of Immunotherapy Resistance

- 1. Weak tumor antigen or loss of tumor-antigen expression
- 2. Upregulation of immune-checkpoint molecules (immune fatigue)
- 3. Activation of alternative signaling pathways
- 4. Immunoediting

## Revealing fresh and possibly stronger tumor antigens would spark and activate the innate immune system



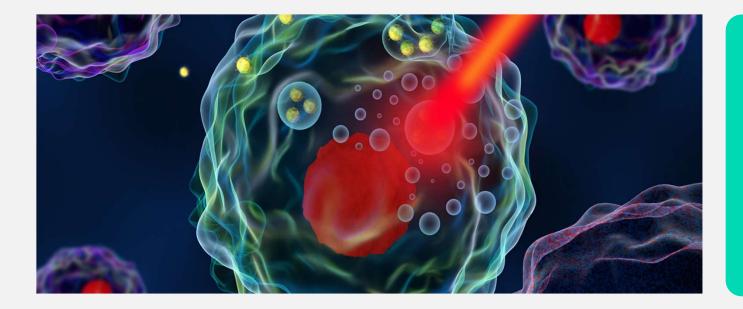
Source: Cancer Resistance to Immunotherapy: Comprehensive Insights with Future Perspectives Sawsan Sudqi Said and Wisam Nabeel Ibrahim, in Pharmaceutics, April 2023

### More of a good thing isn't necessarily better:

Addressing a weak antigen tumor microenvironment with stronger/more IO drugs risks triggering autoimmunity and toxicity

9

## Many Unexposed Antigens Exist in Tumors But How Can Sona Cause Them to be Presented to the Immune System?



Heating cancer cells gently causes them to die by apoptosis which causes the release of neo-antigens

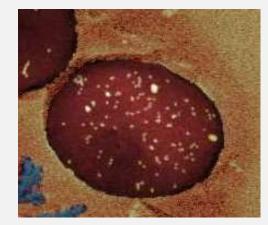
Sona's therapy primes the tumor microenvironment to present neo-antigens, thereby enabling immunotherapy to work better



# Targeted Hyperthermia Therapy ("THT") Uses NIR Light To Heat Nanorod-Saturated Tumors From Inside Out, Gently

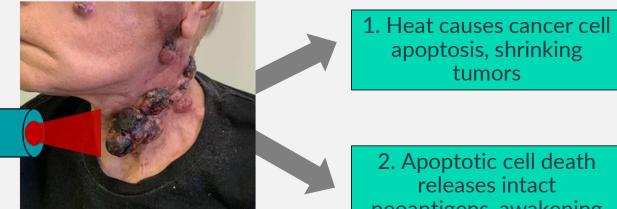
## A Two-Step Therapy

**Inject Biocompatible** Gold Nanorods Intratumorally



Nanoparticles shown in a red blood cell to show relative scale

Shine NIR Light Tuned to 850nm on Tumor



Near infrared light applied to GNR saturated tumor

**Delivering a 1-2 Punch**:

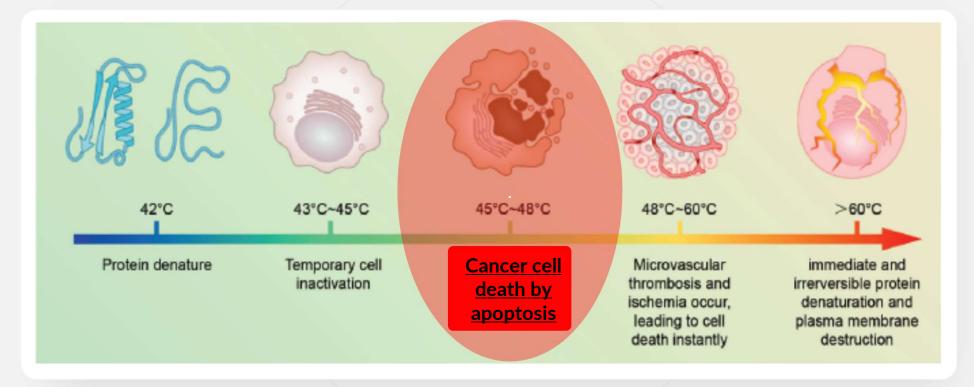
neoantigens, awakening the innate immune system



THT heats the tumor cells gently, shrinking it and causes the exposure of intact tumor-specific neo-antigens

11

# THT's 'Hyperthermia' Approach Heats Tumors to 41-48 °C – Enough to Kill Cancer Cells, But Not Enough to Harm Healthy Cells



**Apoptosis:** A type of cell death in which a series of molecular steps in a cell lead to its death. This is one method the body uses to get rid of unneeded or abnormal cells. The process of apoptosis may be blocked in cancer cells. Also called *programmed cell death*.

(nanotech)

Sources: Adapted from Jiachen Li et al., "Nanoparticles-based phototherapy systems for cancer treatment: Current status and clinical potential," Bioactive Materials 23 (2023), pp. 471 - 507. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/apoptosis

# While Cancer Cell Death by Apoptosis Can Be Stimulated In a Variety of Ways, Sona's THT Therapy is Selective and Efficient

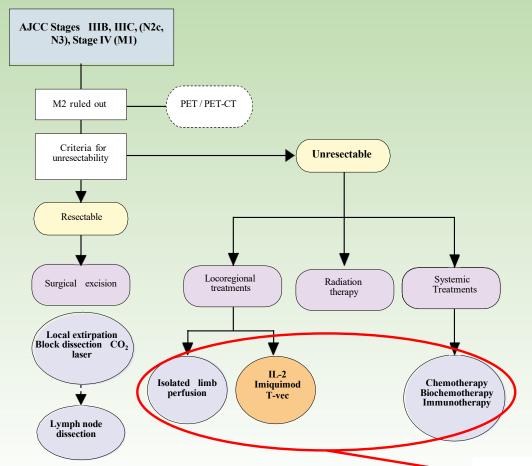
### Rationale for Sona's Targeted Hyperthermia Therapy (THT)

- Gold nanorods (GNRs) are the most efficient gold nanoparticles at converting light energy into heat potentially minimizing therapy times
- Sona's GNRs are uniquely manufactured without toxins, making them an inherently safe and therefore desirable heat generating agent, in vivo
- THT limits healthy cell damage and promotes apoptosis, rather than necrosis by generating moderate hyperthermia instead of high-temperature ablation

## Leverages the innate immune system without 'cutting, burning or poisoning'



## Intended Use Is As Adjunctive To Current Standard Of Care, With The Goal To Become The Standard of Care



### THT Intended Use

- To create hyperthermia in superficial tumors of patients with locally advanced cutaneous melanoma, without distant metastases, as an adjunctive treatment.
- Sites include:
  - Visible/palpable otherwise unresectable melanoma, mucosal melanoma
  - Regions with extensive cutaneous and subcutaneous metastasis *e.g.* numerous in-transit lesions.

**Opportunity for THT Treatment** 

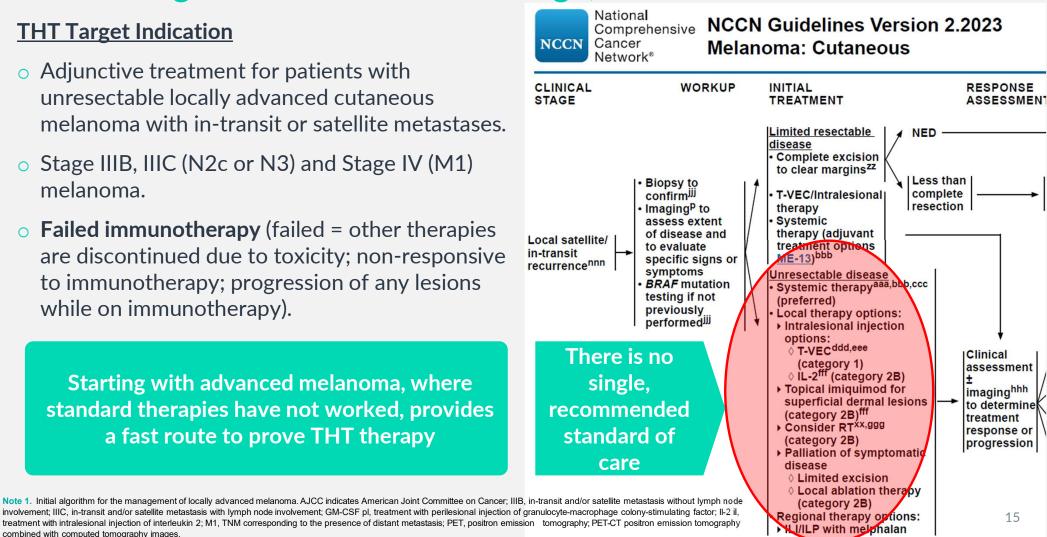
# Initial Target Indication Is Late-stage, Unresectable Melanoma

#### **THT Target Indication**

combined with computed tomography images.

- Adjunctive treatment for patients with unresectable locally advanced cutaneous melanoma with in-transit or satellite metastases.
- Stage IIIB, IIIC (N2c or N3) and Stage IV (M1) melanoma.
- **Failed immunotherapy** (failed = other therapies are discontinued due to toxicity; non-responsive to immunotherapy; progression of any lesions while on immunotherapy).

Starting with advanced melanoma, where standard therapies have not worked, provides a fast route to prove THT therapy



# Sona's THT Therapy is Proprietary And Will Benefit From IP Protection

### Sona's Four Sources of IP Advantage

#### Patents:

- Method for Manufacture of Biocompatible Gold Nanorods • Issued: USA and South Korea. Pending: PCT, Canada, EU. Photothermal NIR LED Light Device • Issued on Dec. 11, 2014, as US patent #10,064,940 Photothermal Near-Infrared Laser Light Device • U.S. Provisional Patent Application No. 63/562461, filed Mar. 7,2024 would also void warranties Gold Nanoparticle Conjugates and Uses Thereof • US patent #9,175,015 filed Aug. 22, 2008 Further provisional patent work underway **Trade Secrets: Time Advantage:**  Moving guickly to maintain Sona's lead to be the first to be approved Techniques for delivery of GNRs in vivo and by regulators application of the non-thermal energy Protocols for immunotherapy agent combinations
- Once approved by regulators, Sona's light device may not be used with 3rd party GNPs
  - Once approved by regulators, Sona's GNRs may not be used with 3rd party light device

**Two Device System:** 

Use of one with a substitute for the other

All restrict off-label use

# Key Elements Of Sona's THT Concept Have Been Proven

# **Previously Done/Approved:**

- Heat used to kill cancer cells
- Photothermal treatment using infrared light devices
- FDA has approved nanoparticles for injection into humans in prior clinical trials<sup>(1)</sup>
- THT efficacy in small animals demonstrated in peer reviewed scientific journal

# Sona's development plan leverages significant prior third-party research



Notes: 1) Aurolase, MagForce and Cytimmune have all received approval to conduct clinical trials for injection of nanoparticles in humans

# Building the Safety and Efficacy Data Required by Regulators for a 'First in Human' Pivotal Phase 1 Clinical Study

#### Current Efficacy Study at Dalhousie University:

Evaluation of Sona Nanotech's Gold Nanoparticle-Mediated Photothermal Therapy in Combination with Intralesional Immune Modulation as a Novel Immuno-Oncology Combination Strategy for Colorectal, Skin and Breast Cancers

<u>Principal Investigator:</u> Dr. Carman Giacomantonio MD, MSc., FRCSC (Cav.)

**Professor**, Faculty of Medicine, Dalhousie University **Surgical Oncologist / General Surgeon**, QEII HSC







## **Research Study Background – Metrics of Success**

## Success Will Be Assessed By The Extent To Which:

#### **Tumor Shrinkage**

- THT causes tumor volume reduction in mouse models of:
  - Melanoma
  - Breast cancer
  - Rectal cancer

#### Enhanced Immune Response

• Use of THT with certain immunotherapies is additive or even synergistic

#### Abscopal Effects are Observed

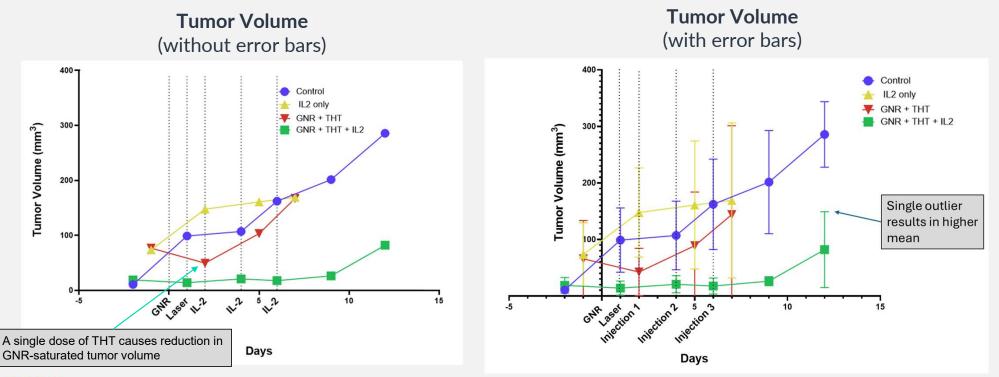
 Immune responses created in remote tumors without directly treating them

Can THT cause a synergistic effect as part of an immunomodulation strategy?



# Initial Data Shows Synergistic Effect of Combining Sona's THT and Standard Immunotherapy Agent IL-2

**Research Study Background – Initial Results** (Triple Negative Breast Cancer Mouse Tumor Model, n=6)





Source: The Giacomantonio Immuno-Oncology Research Group at Dalhousie University

Preclinical Study

# Sona's Development Plan For THT Has Been Guided Of A Panel Of Leading Physicians In The U.S. And Multiple FDA Interactions

#### Stakeholder Engagement

#### **EXCITE International Panel Members:**

- Three surgical oncologists from leading U.S. cancer centres
- Four physicians representing different U.S. payer organizations

#### FDA Pre-IDE Submission Correspondence and Meeting #1:

- Commented on THT pre-clinical development plan
- Responded to questions on target Indications of Use and safety considerations







# Moving Quickly Towards Regulatory Filings and First-in-Human Study



# Sona Has Engineered the Right 'Gene Pool' to Develop Its **Cancer Therapy**





Mark Lievonen Chairman

 Led vaccine maker Sanofi-Pasteur to a billion-dollar value



Walter Strapps PhD Director

 CEO of Khosla Ventures CRISPR/Cas13 biotech



Neil Fraser Director

 Led Medtronic Canada for ~20 vears



Jim Megann Director 25 years of experience in capital markets

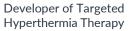
#### Management



David Regan, MBA **Chief Executive Officer** • Capital markets professional • Former strategy consultant



Len Pagliaro, PhD **Chief Scientific Officer** 





Kulbir Singh, PhD Head of R&D Co-Developer of CTABfree gold nanorods



Darren Rowles, MBA Head of Diagnostics • 17 years' experience with nanoparticle diagnostics



Robert Randall, CPA **Chief Financial Officer**  Extensive public company experience





Dr. Carman Giacomantonio

 Surgical oncologist & researcher



Dr. Catherine J. Murphy

Inventor of gold nanorods



Dr. Gerry Marangoni

• Co-developer of CTAB-free gold nanorods

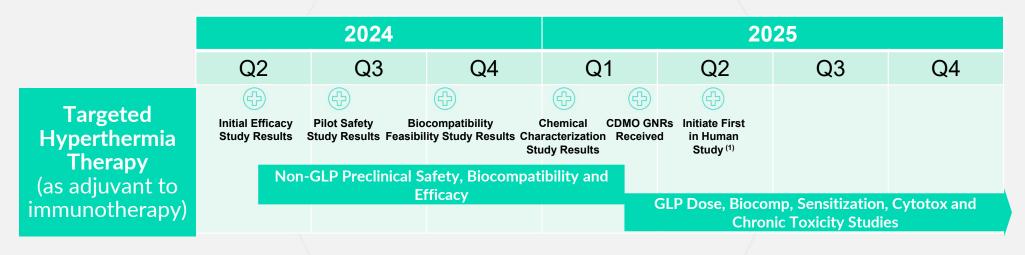


Glenn Kanner, B.Eng., MBA

• Medical device product development consultant

# Key Development Studies For THT Will Provide Many Catatlysts

#### 2024-2025 Anticipated Milestones



## Goal for 'first-in-human' study by 2Q 2025



Note: 1) Assumes overseas first-in-human studies using non-GMP materials.

