

ANNUAL GENERAL MEETING

November 2024

INVION[™]

ASX: IVX

**Next Generation Photodynamic Therapy (PDT)
for Cancers and Infectious Diseases**



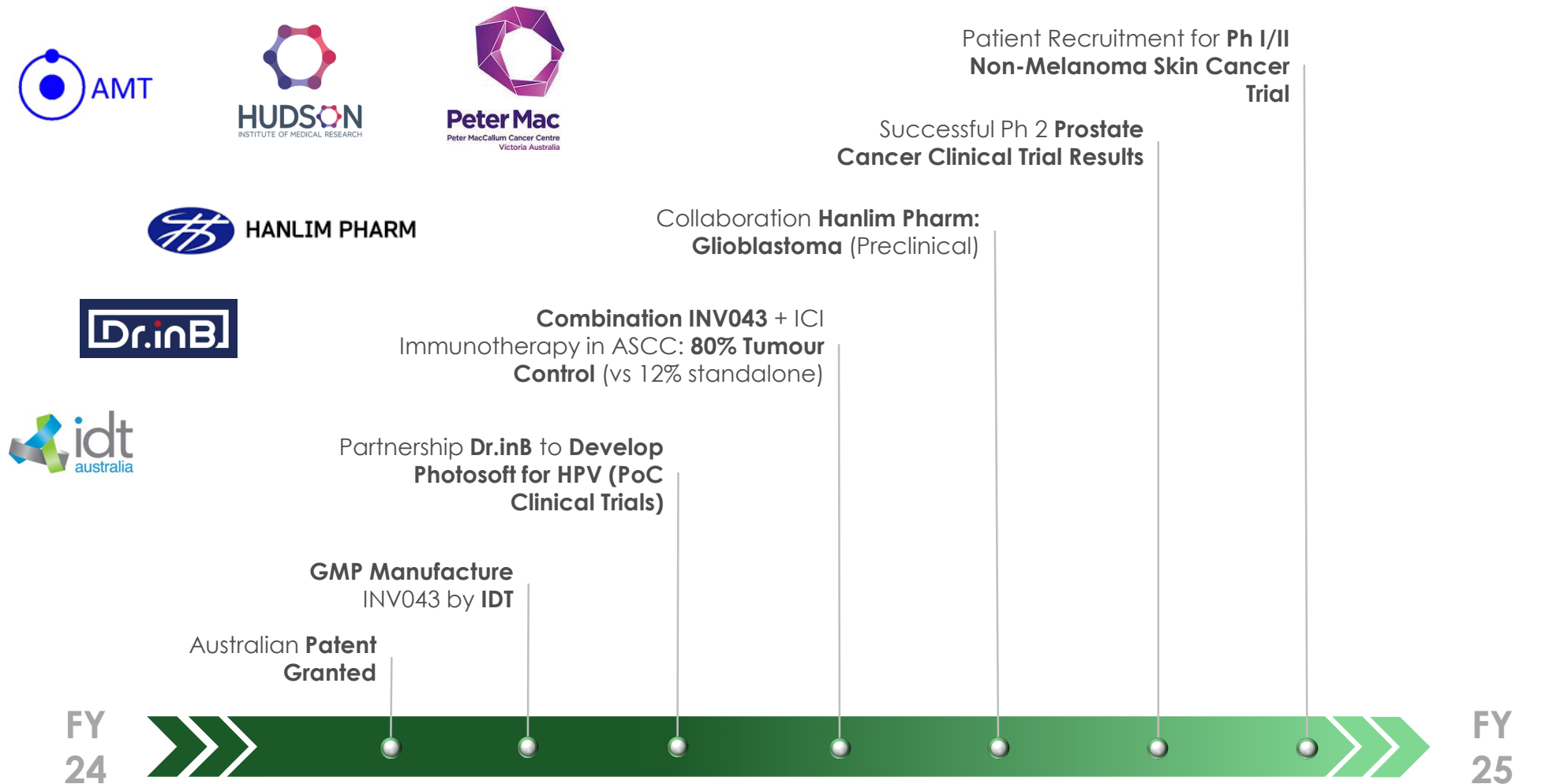
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YEAR OF ACHIEVEMENTS

PROGRESSING TOWARDS KEY CLINICAL MILESTONES



TARGET DISEASES AND INDICATIONS

PDT FOR TREATMENT OF CANCERS AND INFECTIOUS DISEASES*

PRIMARY FOCUS: CANCER (INV043)

- Multiple cancer indications
- Ablation and activation of immune response
- Improved efficacy of immune checkpoint inhibitor (ICI) treatments when in combination
- Topical and systemic formulations
- Strong therapeutic profile

Target Indications

- Non-melanoma skin cancer (topical)
- Prostate cancer (sublingual)
- Anogenital cancer (topical)
- Glioblastoma (GBM): studies undertaken and **funded by Hanlim Pharma**
- Solid tumour cancer TBD (IV)

INFECTIOUS DISEASES

- Broad spectrum antimicrobial activity against viruses, bacteria and fungi
- No known drug resistance (to address AMR)
- Commercially viable focus

Target Indications

- Human Papilloma Virus (HPV): studies undertaken and **funded by Dr.inB**
- Oral antimicrobial: peri-implant mucositis
- Additional TBD



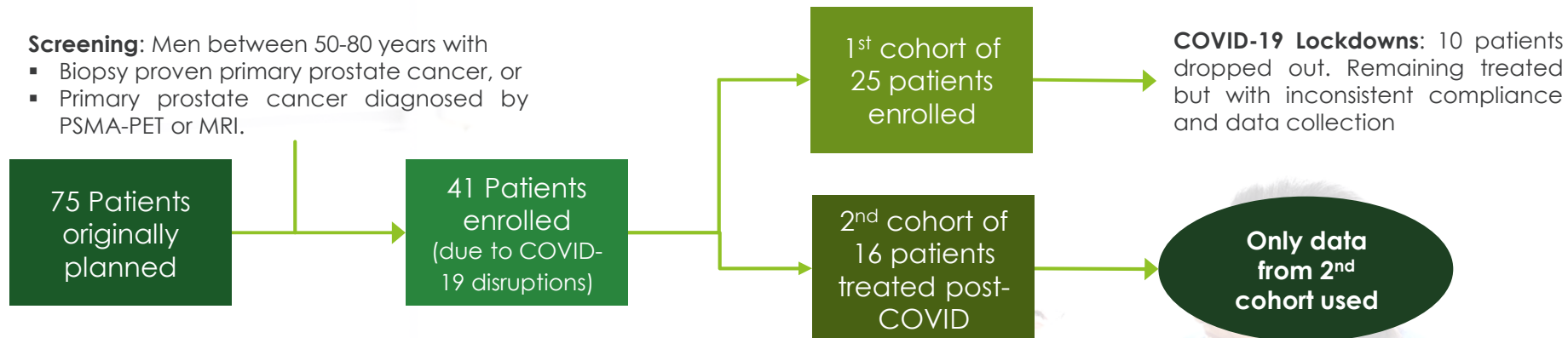
RESULTS AND FINDINGS: CANCER

Clinical & Preclinical Data

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PHASE II PROSTATE CANCER CLINICAL TRIAL

INVESTIGATOR-LED PROSTATE CANCER STUDY USING INV043*



PATIENT PROFILE	PRIMARY ENDPOINT	TREATMENT PROTOCOL
<ul style="list-style-type: none"> • Primary or relapsed localised prostate cancer (diagnosed via biopsy or PSMA-PET) • Ages: 50-70 (mean 62.5) • Baseline Gleason Scores: 6-9 (mean 6.9) 	INV043 PDT treatment effectiveness using Response Evaluation Criteria in Solid Tumours (RECIST 1.1)	Each patient had 6 cycles of PDT treatment over 9 weeks (2 x PDT cycles over consecutive days, then four-week interval) Each PDT cycle consisted of 2 steps.
	SECONDARY ENDPOINTS	
	To assess safety and tolerability as well as further assessments on effectiveness using standard outcome measures	Step 1: Sublingual administration of photosensitiser Step 2: ~15-20 hours after dosing, 25 min of 660 nm laser administered

PHASE II PROSTATE TRIAL RESULTS: SUBLINGUAL (SYSTEMIC)

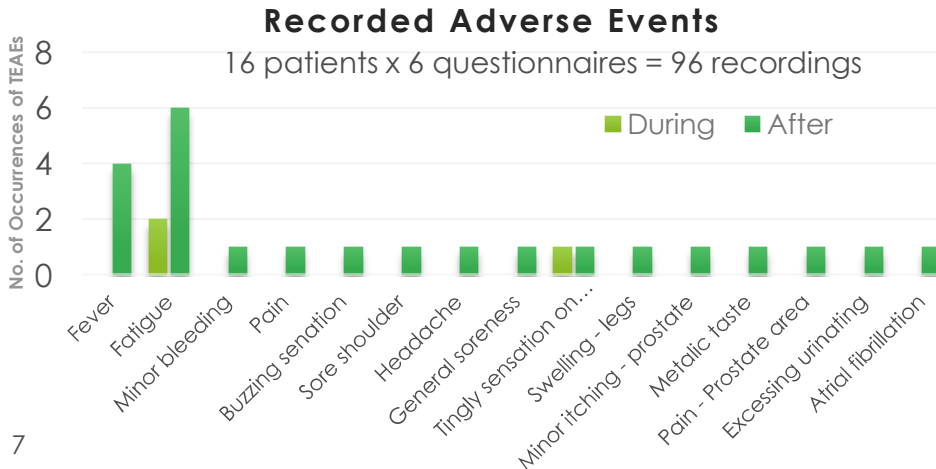
COMPELLING SAFETY, SOLID EFFICACY SIGNALS

SAFE AND WELL TOLERATED

When administered sublingually to patients over **6 cycles of PDT treatments (from 2nd cohort, n=16) over 3 months:**

- No serious adverse events, life-threatening treatment emergent adverse events (TEAEs)
- No clinically significant changes in vital signs, ECGs, or laboratory parameters reported
- **All adverse events reported were mild**

In contrast, current treatment options (eg, radiotherapy, chemotherapy and surgery) carry risks of significant side effects such as incontinence, bowel dysfunction, erectile dysfunction and/or infertility¹



¹ <https://www.pcf.org/about-prostate-cancer/prostate-cancer-side-effects/>

EFFICACY: 40-44% RESPONSE RATE

PSMA-PET¹ Results

Patients (Cohort 2, n=16) evaluated using PSMA-PET scan to detect prostate cancer:

- **BEFORE: All 16 patients were positive before treatment**
- **AFTER: 7 patients negative 3 months after treatment (~44% response), 9 patients were positive**

RECIST Framework³ (Response Evaluation Criteria)

Where possible, MRI scans taken pre and post treatment to measure lesion size in prostate (n=10)²

- **40% patients had +ve response 3 mths post treatment**
 - 1 complete regression (no detectable lesion)
 - 3 partial regression (>30% reduction in lesion size)
- 40% patients showed stable disease
- 20% with disease progression (>30% lesion increase)

¹ PSMA PET-CT now routinely used to evaluate prostate cancer for primary staging and suspected tumour recurrence (Combes AD, 2022). Employs radioc targets PSMA (prostate-specific membrane antigen) protein expe

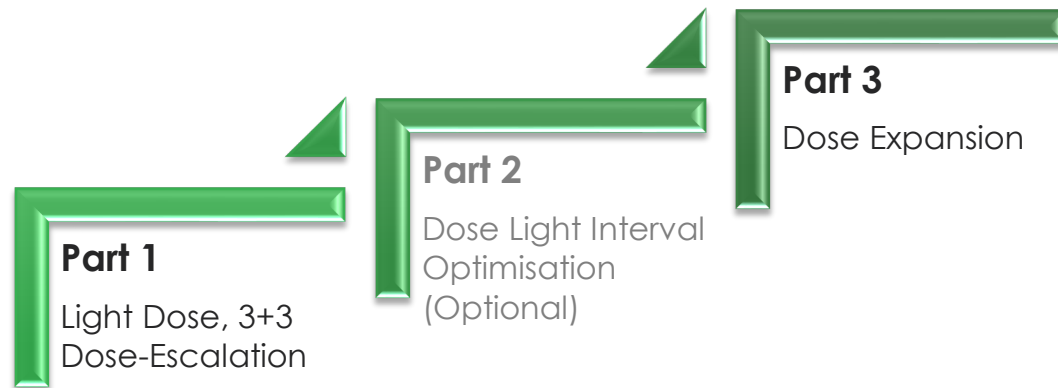
² Two received prostatectomy prior to PDT treatment and were ex have MRI scans for various reasons (eg, presence of implants) anc

³ <https://recist.eortc.org>

ONGOING PHASE I/II TRIAL: NON-MELANOMA SKIN CANCER

THERAGNOSTIC ENDPOINTS

- **Adaptive:** Open label adaptive trial design (3+3 light dose / dose light interval escalation¹) enables flexibility in size and timing, with option for repeat treatment depending on response
- **Safety, Dose Optimization and Efficacy:** Earlier parts focus more on safety and tolerability, later parts more on dose and schedule optimization, and efficacy. Multiple treatments may be repeated for patients
- **Significant Unmet Need:** Cutaneous Squamous Cell Carcinoma (cSCC) and superficial Basal Cell Carcinoma (sBCC), 98% of all skin cancers – one of the world's most common cancers



ENDPOINTS

- **Safety and tolerability** including Dose Limiting toxicity (DLT)
- **Dose optimization:** Light dose, dose light interval investigations
- **Anti-tumour activity**
- **Diagnostic** via fluorescence
- Pharmacodynamic investigations

Ongoing screening and recruitment in Australia for NMSC trial using topical formulation

¹ In a "3+3 design," three patients are initially enrolled into a given dose cohort. If there is no DLT (dose limiting toxicity) observed in any of these subjects, the trial proceeds to enroll additional subjects into the next higher dose cohort.

WHY SKIN CANCER?

ATTRACTIVE CLINICAL TRIAL INDICATION

Relatively Cost Effective



Costs to undertake skin cancer trials typically lower than for other routes of administration (eg, intravenous)

Faster Path to Market



Trials with topical treatments often quicker to complete due to fewer safety concerns and effects can be more readily observed

Synergies with Other Studies



Safety data from same topical formulation may enable a faster path to a Phase II trial for anogenital cancers

Large Attractive Market



One of the world's most common cancers with the skin cancer treatment market expected to hit US\$18.1B in 2030 (7.7% CAGR¹)

Unmet Medical Need



NMSC comprise 98% of all skin cancers and deaths exceed melanoma globally² Standard of care can result in scarring and pain

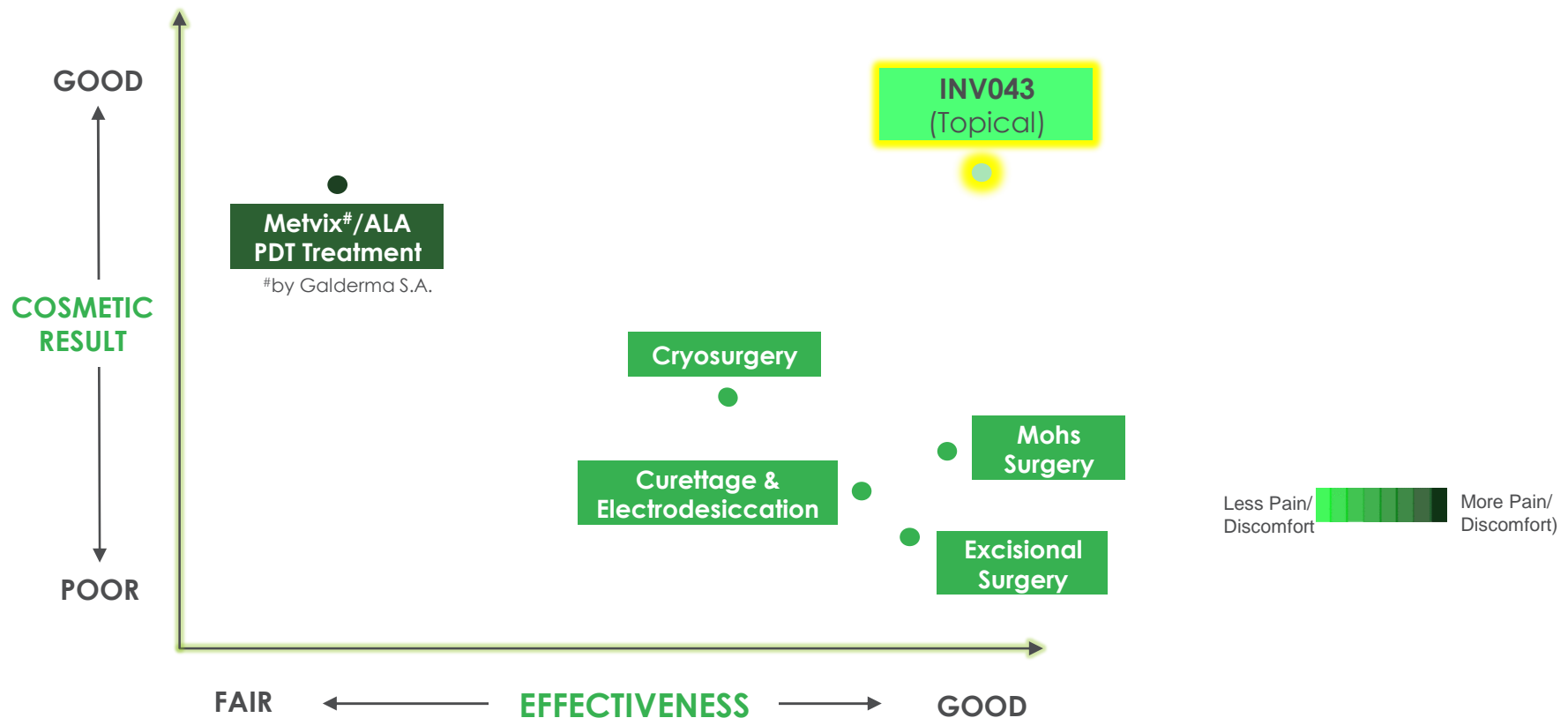
¹ <https://finance.yahoo.com/news/skin-cancer-treatment-market-surpass-130500291.html>

² GLOBOCON 2020, WHO

EVALUATION OF NMSC THERAPIES¹

POTENTIAL TO DISPLACE STANDARD OF CARE

Non-Melanoma Skin Cancer (NMSC) Phase I/II Clinical Trial (Adaptive Trial Structure):
Addressing the unmet need for one of the world's most common cancers²



¹ Based on management views

* <https://www.aad.org/news/guidelines-to-treat-nonmelanoma-skin-cancer>

* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5746716/>

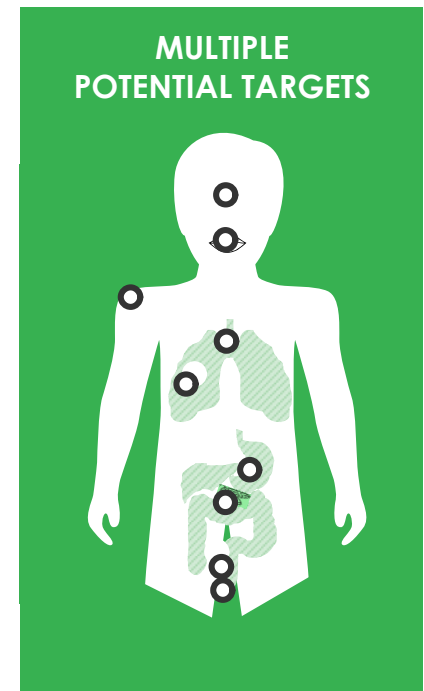
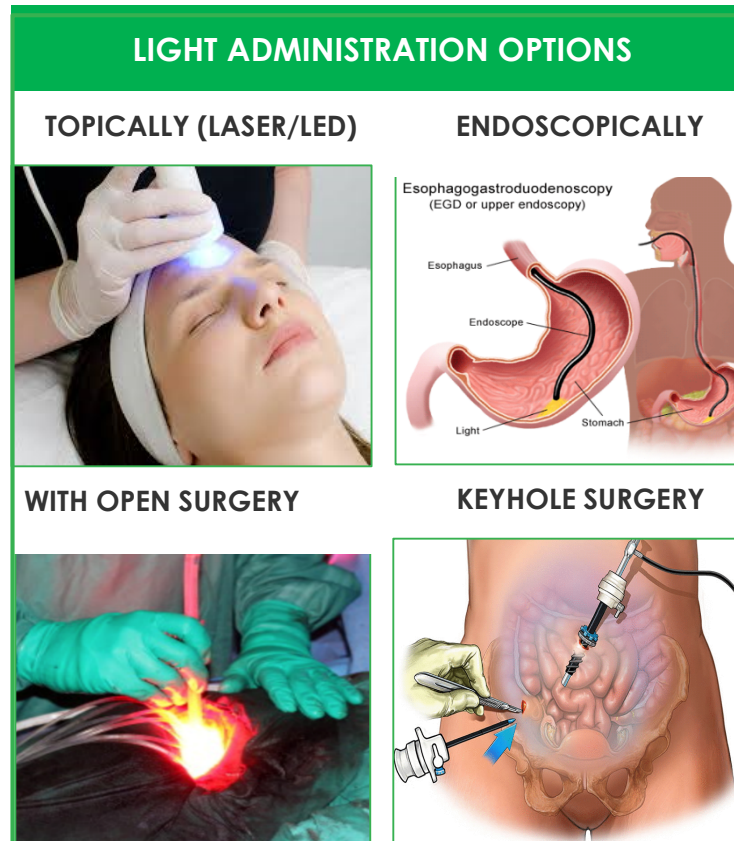
* <https://amp.cancer.org/cancer/types/melanoma-skin-cancer/about/key-statistics.html>

² <https://amp.cancer.org/cancer/types/melanoma-skin-cancer/about/key-statistics.html>

TREATMENT OPTIONS: FLEXIBILITY FOR CLINICIANS

MULTIPLE PATHWAYS FOR DRUG AND TARGETED LIGHT DELIVERY

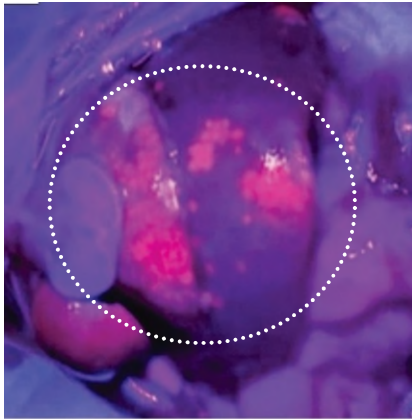
INV043 can be administered to multiple target indications via different drug and light delivery options



THERAGNOSTIC POTENTIAL

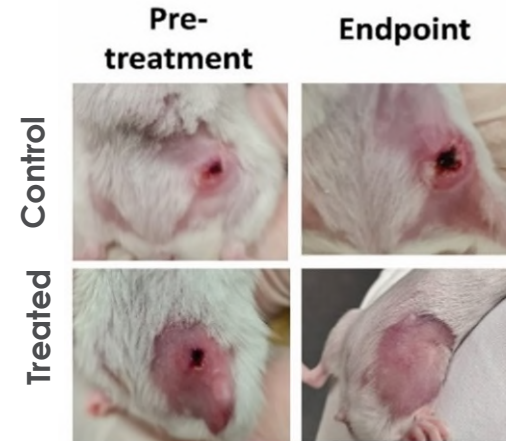
MULTIPLE CANCERS, PRECISION CANCER TARGETING, PROTECTIVE IMMUNITY

SELECTIVE TARGETING



- INV043 **selectively retained** in malignant but not healthy tissue, **across multiple cancers** (incl. pancreatic, triple-negative breast, T-cell lymphoma *in vivo*)
- **Minimises collateral damage** to healthy organ tissues with no notable toxicity issues
- INV043 has both **fluorescence** as well as **ablation** characteristics (under different wavelengths of light)
- Applications in both diagnostic (405nm) and therapeutic use (660nm) – **theragnostic potential**

PROTECTIVE IMMUNITY



<https://inviongroup.com/videos-reports/>

- Triple Negative Breast Cancer (TNBC) is a hard-to-treat cancer resistant to most chemotherapies
- Hudson Institute proof-of-concept (PoC) pilot showed **complete regression of TNBC** *in vivo* following INV043 treatment
- Tumour mass undetectable two weeks after initial treatment and no scarring evident
- No recurrence of disease, re-challenge with TNBC implant could not re-establish new tumours, suggesting development of **protective immunity**

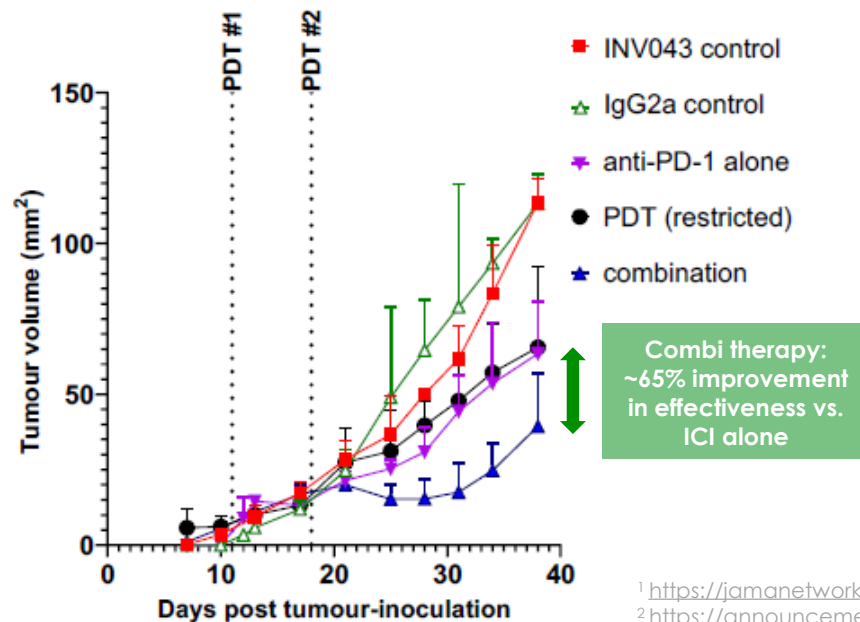
COMBINATION WITH IMMUNE CHECKPOINT INHIBITORS (ICI)

IMPROVING IMMUNOTHERAPY OUTCOMES, PARTNERSHIP POTENTIAL

- Immune checkpoint inhibitors (ICI), a type of immunotherapy, is standard of care in treatment of several cancers
- Despite widespread use of ICIs, the patient response rate can be as low as 12.5%¹**
- Independent *in vivo* studies showed **combined INV043 and anti-PD-1** therapies achieved 80% tumour elimination

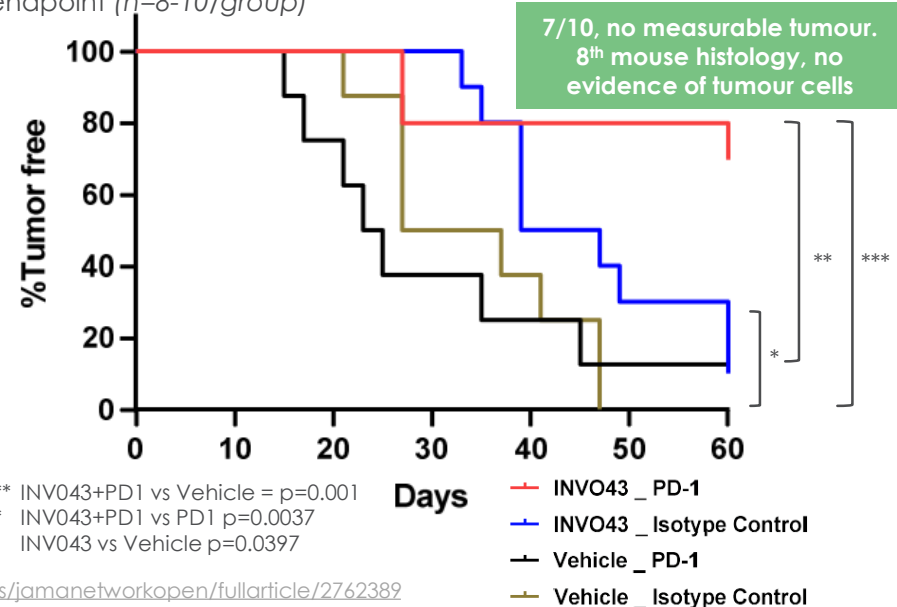
HUDSON INSTITUTE: ~65% IMPROVEMENT IN TUMOUR VOLUME (TRIPLE NEGATIVE BREAST CANCER, INTRATUMORAL)²

- 4T1 breast tumours treated using a restricted INV043 PDT protocol (intratumoural) and / or anti PD-1 antibody (intratumoural)
- Monotherapies restricted tumour growth vs untreated controls
- Combination therapy regressed and stabilized tumours and achieved a ~65% reduction in tumour size at endpoint ($n=4/\text{group}$)



PETER MAC: ~80% RESPONSE RATE (ANAL SCC CANCER, TOPICAL)³

- Anal Squamous Cell Carcinoma (ASCC) tumours treated using a restricted INV043 PDT protocol (topical) and / or anti PD-1 antibody
- Monotherapies restricted tumour growth vs untreated controls, with standalone INV043 showing lower tumour volume vs ICI alone
- Combination therapy resulted in 80% tumour-free subjects at endpoint ($n=8-10/\text{group}$)



¹ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2762389>

² <https://announcements.asx.com.au/asxpdf/20220530/pdf/459ffkjbdpjr.pdf>

³ Per ASX announcement 4 March 2024

CREATING IMPACT FOR TREATING CANCERS GLOBALLY

NEED FOR MORE AFFORDABLE NEW TREATMENTS

Cost of new FDA drugs in 2023 jumped 35% YoY at median price of US\$300K¹, making affordability even harder for the majority of the world's patients.

Trends towards personalised medicines and targeted therapies (e.g. CAR T / cell therapies, immunotherapies, antibody drug conjugates which can cost US\$100-500k²),

Half of new drugs are orphan³, which cost 5.5 times more than non-orphan⁴

Commercial Rationale for Photosoft™



Works across multiple cancers without need to personalise – precision with less complexity



INV043 is a small molecule based therapy that is highly scalable



Photosoft solution has lower development and manufacturing costs



Equipment and treatment process is not complex - helps reach a larger patient base

¹ <https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/>

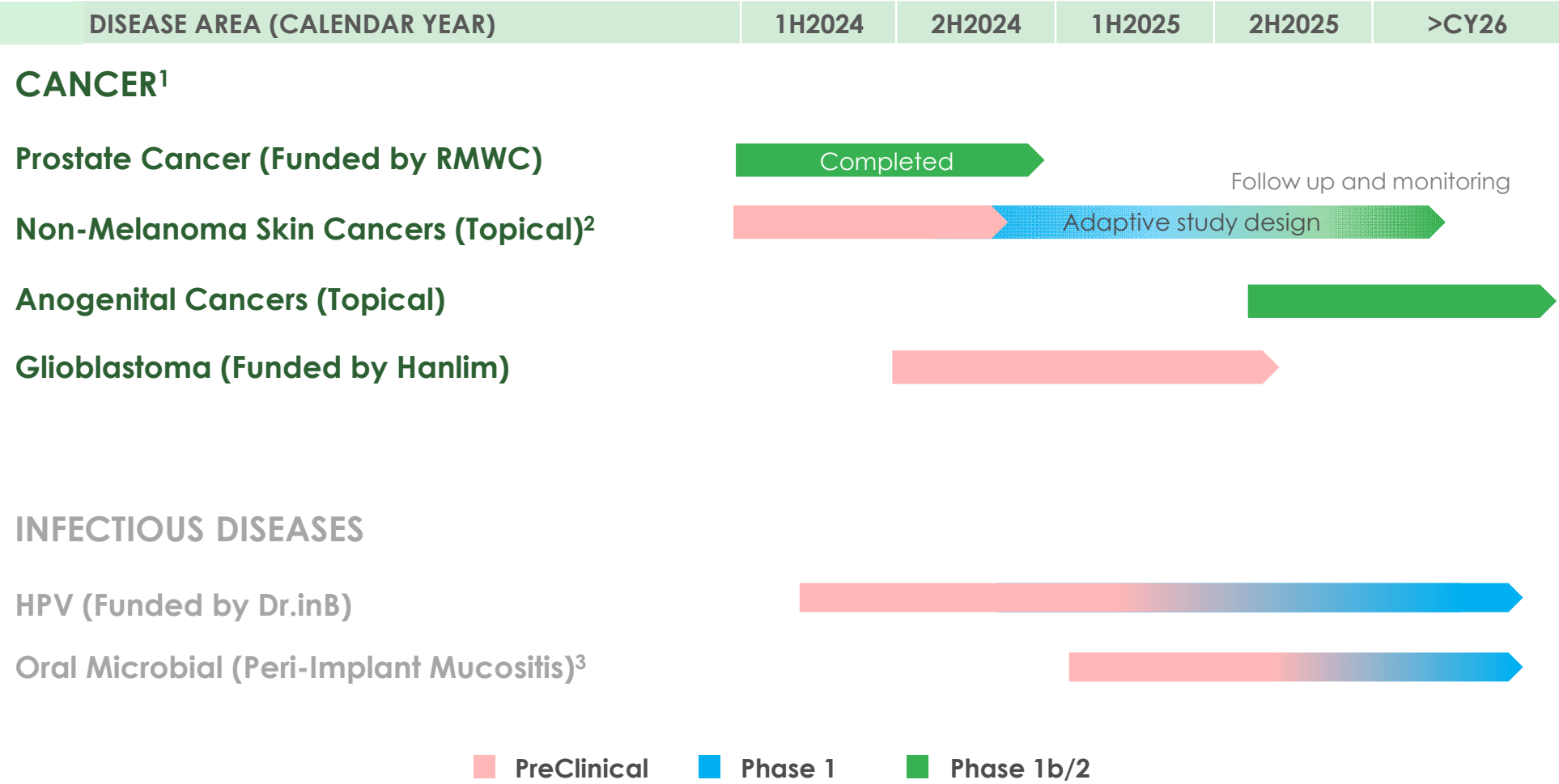
² <https://www.mdpi.com/1999-4923/15/6/1761#:~:text=Additionally%2C%20the%20cost%20of%20ADC,a%20barrier%20for%20some%20patients>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10290406/#:~:text=There%20has%20been%20significant%20policy,being%20approved%20in%20recent%20years>

⁴ <https://www.mdpi.com/1999-4923/15/6/1761#:~:text=Additionally%2C%20the%20cost%20of%20ADC,a%20barrier%20for%20some%20patients>

TARGET INDICATIONS AND TIMEFRAMES

MULTIPLE CLINICAL TRIALS AND INDICATIONS





INFECTIOUS DISEASES

Additional Commercialisation Opportunities

INVION[™]

BROAD-SPECTRUM ANTI-MICROBIAL POTENTIAL

ANTI-MICROBIAL TREATMENTS – WITHOUT RESISTANCE

“Antimicrobial resistance (AMR) is one of the top 10 threats facing humanity”

World Health Organisation¹

Leading Institutions: Viroclinics conducted virus tests & ACARE (University of Adelaide) conducted bacteria and fungi tests

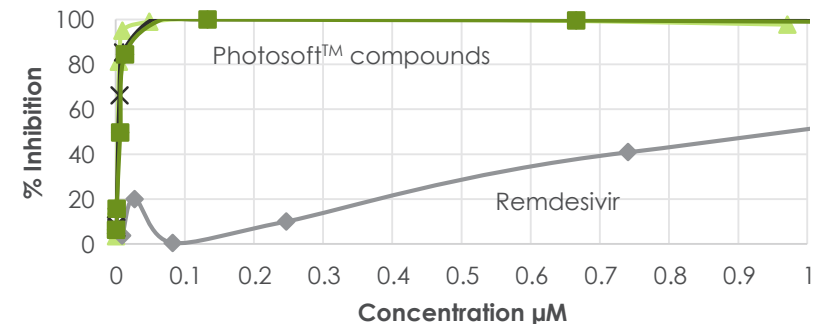
Broad Spectrum Potential: *In vitro* tests showed Photosoft™ to be effective against several types of pathogens, including antibiotic-resistant superbugs

Need for New Treatment Options: Potential for Photosoft™ as a new treatment class for polymicrobial infections and/or where pathogens cannot develop drug resistance

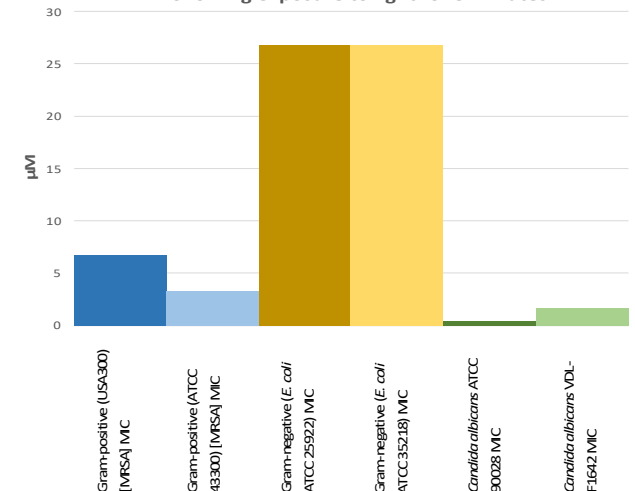
“ Given the general mode of action of PDT... it is unlikely for superbugs to develop resistance to the compounds ”

Prof Darren J. Trott, Director, Australian Centre for Antimicrobial Resistance Ecology (ACARE), University of Adelaide

SARS-CoV-2: Omicron
Selected Photosoft™ Compounds vs. Remdesivir



Broad Spectrum Activity: Minimum Inhibition Concentration (MIC50) of Selected Photosoft Compound following exposure to light for 5 minutes

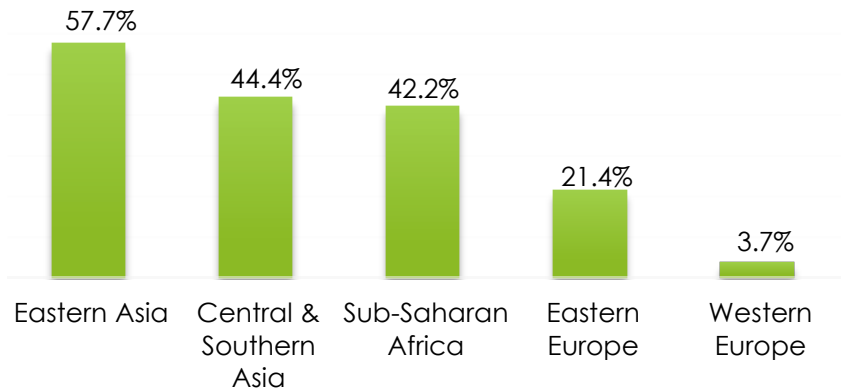


TARGET ANTIMICROBIAL INDICATIONS

COST EFFECTIVE AND ACCELERATED PATHS TO CLINICAL TRIALS

HPV PROGRAM FUNDED BY DR.INB

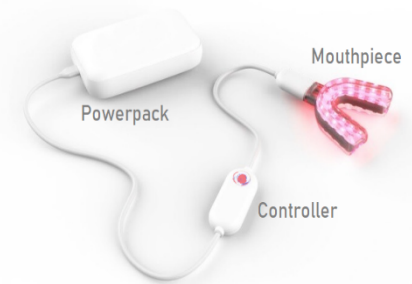
HPV distribution profile in women¹



Collaboration

- **Undertake and fund to Proof-of-Concept clinical trials** to test patient safety and efficacy (using different Photosoft™ photosensitizer than INV043)
- Dr.inB is a leading developer of PDT treatments in South Korea backed by Hanlim Pharma. Co., Ltd.
- Collaboration provides **accelerated pathway to demonstrate clinical potential** of Photosoft in infectious diseases like HPV
- **Invin retains all rights** to Photosoft and any new IP

PERIODONTAL DISEASE



Addressing a Growing Unmet Need

- Per CDC, **47.2% in US >30 years, have a form of periodontal disease**, increasing 70.1% of those >65 years²
- Global periodontal market size US\$ 9.1 billion in 2022, to reach ~US\$ 24.4 billion by 2032³
- **28-56% of implant patients develop peri-implantitis⁴**, an inflammatory reaction, with loss of supporting bone around an implant
- **Photosoft™ PDT advantages**
 - No resistance development
 - Non-invasive treatment
 - Ease of application
 - Repeated treatment possible

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18 ¹ <https://www.sciencedirect.com/science/article/abs/pii/S0264410X12010808>
² <https://www.cdc.gov/oralhealth/conditions/periodontal-disease.html>
³ <https://www.futuremarketinsights.com/reports/periodontal-market#:~:text=Periodontal%20Market%20Size%20%2D%20Industry%20Outlook,billion%20by%20the%20year%202032>
⁴ <https://pubmed.ncbi.nlm.nih.gov/18724856/> and Carl E. Misch 4th Edition

EXPERIENCED TEAM

THE RIGHT EXPERTISE FOR SUCCESS



PROF THIAN CHEW
EXECUTIVE CHAIRMAN & CEO

- Co-Founder, Chronic Airway Therapeutics
- Advisory Board, Stanford Medicine CARE
- Executive Director, Goldman Sachs
- Director, KPMG Consulting, Senior Manager KPMG
- Adj. Prof. HKUST, MBA/MA Wharton School



DR AMY PRAWIRA
MEDICAL CONSULTANT

- Founder/CEO, Obatica Pty Ltd (engaged to assist with clinical trials)
- 12+ years in clinical oncology and trials
- Investigator with experience in over 90 early phase clinical trials
- Head, Cancer Trials and Research Unit, Prince of Wales Hospital (Sydney)



KIM STEEL
CLINICAL TRIAL MANAGEMENT

- 18+ years managing global and clinical drug and device studies from Phase 1-IV across 14 countries
- Managing Director, SAPRO Consulting
- Project Director, Novotech
- Project Manager, Pacific Clinical Research Group



ALEXANDER BENNETT
TECHNICAL ADVISOR, LIGHT DEVICES

- 35+ years in R&D, manufacturing and commercialisation of scientific instrumentation incl. ISO certifications
- GM Forensic Light Sources, Rofin Australia.
- Led Medical Light Source trial for PDT in skin cancers Peter MacCallum Cancer Centre



SCOTT CARPENTER
PROGRAM DIRECTOR

- Director Business Development, Starpharma
- Program Manager, AusBiotech
- Regulatory Affairs, Bayer CropScience
- MBA Melb Business School, B. Applied Science RMIT



DR SOUMYA RAI
PROGRAM MANAGER

- Dental surgeon, clinical and business mgmt experience
- Resident, JLN House and Research Centre, SAIL
- Asst Prof. Rungta College Dental Sciences and Research
- MBA HKUST



PROF SEBASTIAN MARCUCCIO
MEDICINAL CHEMISTRY

- 35+ years in pharmaceutical/organic chemistry drug discovery and development (co-inventor recent PDT patents)
- Founder / Director Advanced Molecular Technologies
- Previously in Pharmaceutical Chemicals Research, CSIRO
- Adj. Prof. La Trobe University, PhD Organic Chemistry ANU



LOUISE WHITE
MANUFACTURING AND QUALITY

- 35+ years in the pharmaceutical industry, 13 years in vaccine manufacturing, CSL, Partner SeerPharma
- Experience in virology R&D, bacterial vaccines production, quality control and production planning
- Registered auditor for APVMA



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