Medi-Solfen Pty Ltd

Corporate profile 2025

Medi-Solfen®

Contents

Our vision

To create and provide products that are cost-effective, practical, and capable of alleviating pain, aiding in the healing process, and minimizing suffering associated with wounds in humans.

Our mission

We are committed to ending unnecessary wound pain and reducing wound-related morbidity and mortality.

Our strategy

Medi-Solfen Pty Ltd is a cutting-edge life science research-oriented enterprise poised for exceptional success. As a commercial development company, we specialize in working closely with handpicked distributor partners to pioneer and cultivate emerging markets for groundbreaking products designed to alleviate the distress and anguish caused by wounds.

Our strategic approach involves leveraging licensing agreements, including private label arrangements, to expedite the expansion of our research, intellectual property, and product development initiatives. This deliberate expansion allows us to establish ourselves as preeminent global experts at the vanguard of mitigating human pain and suffering associated with wounds.

In 2022 Medi-Solfen Pty Ltd was created, to exclusively license the human IP from the Medical Ethics Group, optimising its potential as a standalone human life sciences company.

See pages 02–07

The Medi-Solfen® product pipeline is focused on mitigating pain and minimising suffering from wounds.

See pages 14–21

The Global Wound Care Market is expected to grow at a CAGR of 4.12% to reach an estimated value of AUD 46.3 billion by 2030.

See pages 12–20

Foundation for success: The first and only topical pain and wound management product for animals.

Medical Ethics are the first, and currently the only, company globally to develop, launch and commercialise a topical pain and wound management product, setting a new standard for animal welfare.

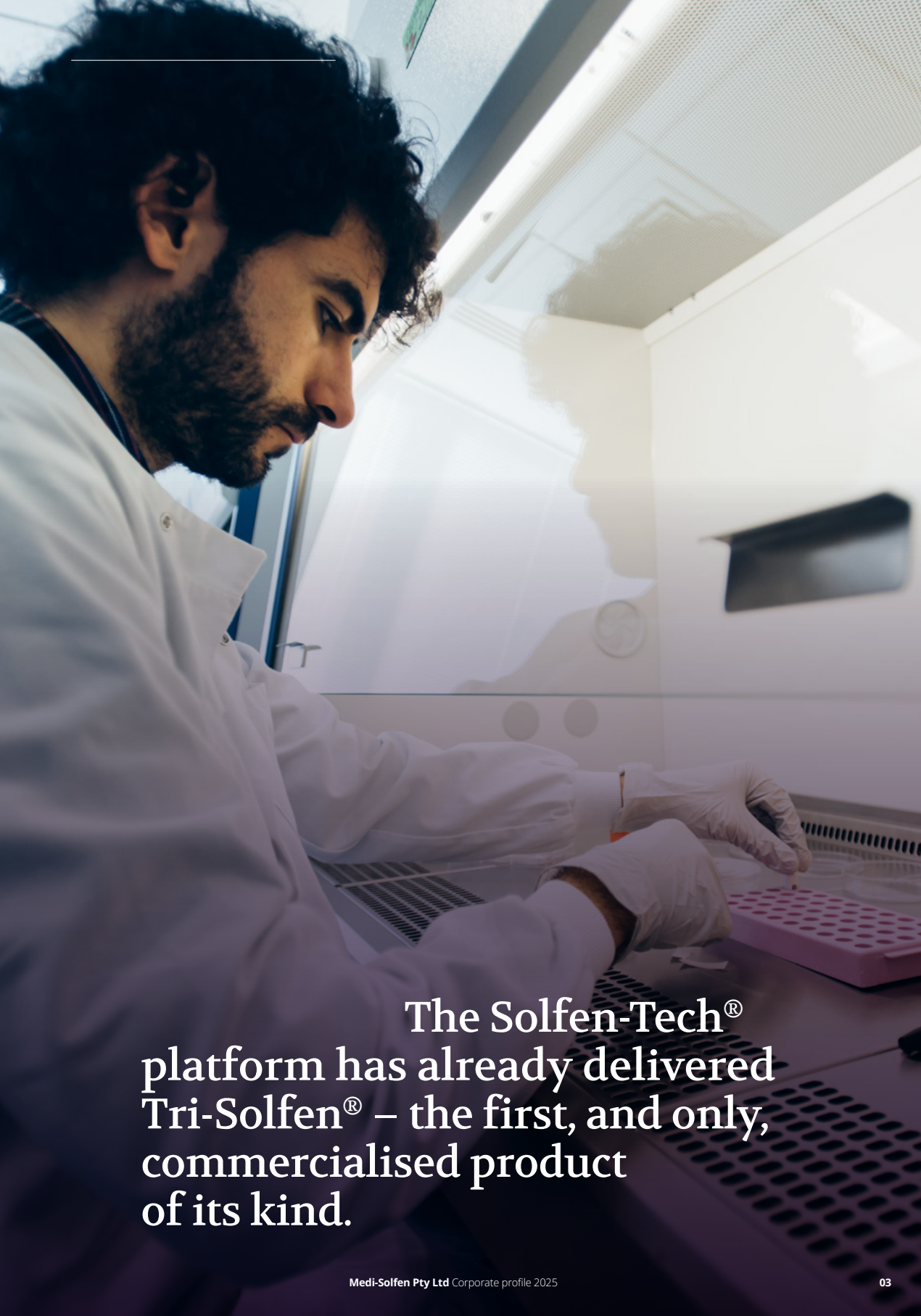
Tri-Solfen® is the first product developed from the Medical Ethics Solfen-Tech® platform, which has been successfully commercialised for use on animals. The proven patented platform technology that has been developed is a transformational way of mitigating pain and suffering associated with wounds in animals.

The Solfen-Tech® technology provides critical wound care for surgical procedures in sheep, pigs, cattle, equine and companion animals. The painful surgical procedures include dehorning, tail docking, castration, and fly-strike prevention.

The group has successfully registered Tri-Solfen® in Australia, New Zealand, the United Kingdom, Portugal, Canada, Brazil and Mexico with registrations pending in several other countries including the European Union and United States.

>200m

Animals treated
Over 200m animals have been treated with Tri-Solfen® since 2006



The Solfen-Tech® platform has already delivered Tri-Solfen® – the first, and only, commercialised product of its kind.

1st

First patients successfully treated

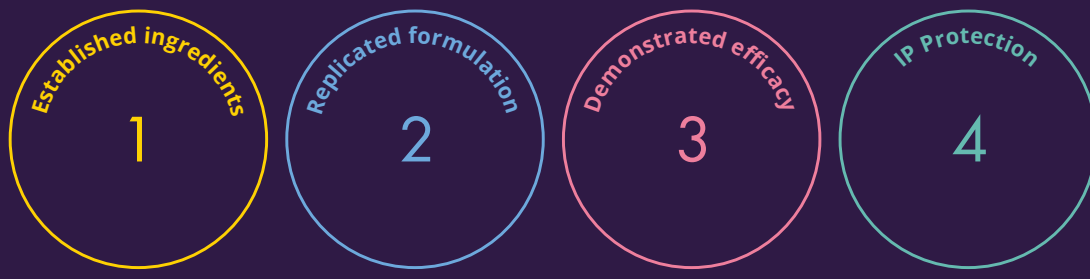
In January 2025, the first patients were successfully treated as part of the Phase II Laceration Studies conducted in the Emergency Department (ED) and Phase I Unit in Kyiv, Ukraine.

Our quest is to enter the human market with our leading pain mitigation and accelerated wound healing platform technology.

Offering a patient focused solution to advance the standard of care for chronic and acute wounds, the technology has been developed as a topical "spray and stay" formulation providing several benefits when applied including pain relief, reduced bleeding and anti-bacterial activity.

Future near-term opportunities for the human proprietary product Medi-Solfen® include the treatment of traumatic wounds caused by surgical procedures, and mass trauma situations such as accidents, military conflict and natural disasters.

Medi-Solfen® has significantly reduced commercialisation risks.



The individual active ingredients of Medi-Solfen® are well established globally and used widely in human care and extensive proof of efficacy already exists.

Medi-Solfen® utilises the same APIs and replicates the same formulation as Tri-Solfen®, an already successful commercialised product.

The efficacy of Tri-Solfen® in veterinary indications has been demonstrated.

Technology is secured by registered patents in key jurisdictions including, the USA, Australia, NZ, the EU and Canada.

The commercialisation risks for Medi-Solfen® have been significantly reduced, allowing the registration of Medi-Solfen® to be accelerated to Phase II trials, bringing forward commercialisation outcomes.

Phase II trials for applications of Medi-Solfen® on Laceration and Leg Ulcers commence in Q1 2025 and Q2 2026 respectively.

Company timeline

'04

Dr Sheil and the Medical Ethics team developed Tri-Solfen®.

2004

2005

Tri-Solfen® was approved for commercial release by the APVMA for use on sheep undergoing mulesing in Australia and the patent for platform technology was secured.

Additional patents have since been granted in Australia, New Zealand, the EU, Canada and the USA.

2006

Tri-Solfen® was officially launched onto the market. Bayer Animal Health secured the Australian license for sheep.

2008

Medical Ethics secured a prestigious Australian Research Council linkage grant with Sydney University and Bayer Animal Health for $2.1m.

2009

Global retailers and animal welfare groups lobbied the Australian government for the mandating of Tri-Solfen® for use on sheep.

2012

Tri-Solfen® was registered for use on sheep by the APVMA.

2013

November

Bayer, Sydney University and MLA1 signed a collaboration agreement to develop a castration and dehorning product from the Medical Ethics platform IP.

December

Tri-Solfen® was granted OTC status and expanded distribution to 30,000 wool-growers.

2014

The IP was granted patent protection in the lucrative USA market, expanding patent protection to over 20 countries.

Professor Temple Grandin, the world's foremost animal welfare scientist and advisor to global retailers such as McDonald's, called for the fast tracking of Tri-Solfen® registration in the USA.

2015

Sydney University published studies that proved efficacy and safety in both cattle and pigs.

Bayer Australia expanded the license agreement to IP, which included cattle pain relief products from the Medical Ethics platform.

The journey so far

2016

February

The Australian government and the Rural Development Corporation nominated Tri- Solfen® as the number one registration priority for all livestock industries.

The Australian Wool Industry committed $900k in funding to develop Tri-Solfen® for all sheep husbandry procedures.

September

APVMA approved registration for castration and tail docking in all sheep breeds.

October

The second USA patent was granted for all species, including humans.

APVMA approved registration for castration in cattle, the first topically applied product approved globally for this procedure.

2017

January

Tri-Solfen Technology was awarded the Best New Global Animal Product at the prestigious AnimalPharm awards.

February

MHRA prescientific advice confirmed acceptable data to proceed to phase 2 human studies in 80 clinical patients.

March

Dechra Pharmaceuticals purchased 33% equity.

April

Dechra investment accelerated animal regulation requirements & the phase II human clinical study.

Wales Wound Institute agreed to be the lead investigator for the human clinical study.

2018

June

Bayer NZ appointed as license partner and the Cattle Disbudding Claim was approved in Australia for dairy and beef.

March

Dechra PLC increased shareholding to 49.5%, and in a separate transaction, secured ANZ license rights for $31m.

2021

July

Medical Ethics Board approved the demerger of Medi- Solfen® and the licensing of all IP with Human indications to the new entity with a view of an IPO on the ASX.

2025

January

First Patients Successfully Treated in Phase II Laceration Studies. Conducted in Emergency Department (ED) and Phase I Unit, Kyiv, Ukraine.

‘25

Demonstrated and established

Demonstrated commercial success

***Based on published trial data**

Well-established

Medi-Solfen® (Tri-Solfen®) is a well-established veterinary anaesthetic with a proven track record. It has been widely utilized for anesthetizing acute open wounds in sheep, pigs, and cattle, both during and after surgery, with extensive veterinary clinical trial data supporting its efficacy.

The active ingredients used in Medi-Solfen® have a solid clinical reputation. They are widely recognized as effective anaesthetic agents, having been used both individually and in fixed combinations of two or more of these actives.

Potential to revolutionise

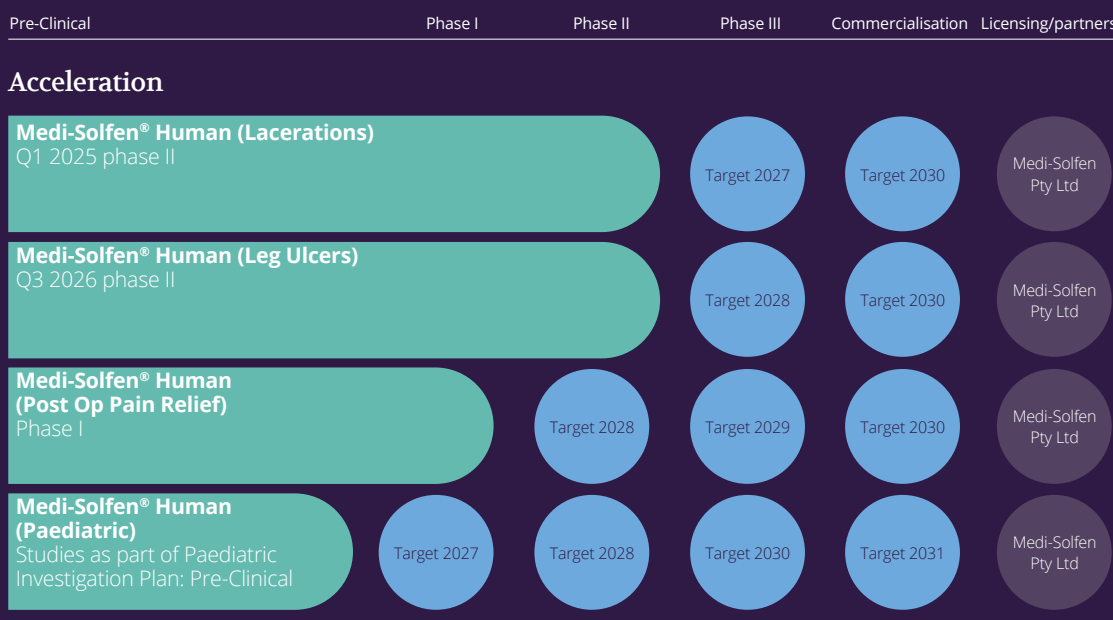
Medi-Solfen® has the potential to revolutionise the management of open wounds in humans, in the same manner that Tri-Solfen® has demonstrated in over 200 million animals. The data from animal studies supports that Medi-Solfen® may be equally safe and effective for use on humans.

Extensive proof of principle

In this context, demonstration of clinical efficacy and safety of Medi-Solfen® used in open chronic wounds and acute wound scenarios is considered lower risk than standard pharmaceutical developments, as extensive proof of principle already exists both with the actives in humans and in similar wound types.

Phase 2 human studies of Medi-Solfen® have recently commenced with the successful treatment of the first patient at an Emergency Department (ED) and Phase I Unit, Kyiv, Ukraine.

Pipeline and patents



40+ Patents

Medi-Solfen Pty Ltd has the commercial rights to 40+ patents in key global markets, with several new patents pending, providing protection until 2042.

Patent Family 1; Title: A Topical Anaesthetic Composition; Claims Tri-solfen and like formulations

Patent Family 2; Title: A Topical Analgesic Composition; Claims the extended analgesic effect of Tri-solfen and like formulations

Patent Family 4; Title: Topical Anaesthetic Composition Having Improved Vasoconstrictor Stability; Claims adrenaline stabilised Tri-solfen and like formulations

Patent Family 5; Title: Sterile Stable Pharmaceutical Composition; Claims sterilised Tri-solfen and like formulations

Patent Family 6; Title: Method of Disease Control; Claims potential application of Tri-solfen to treat humans for one or more of foot and mouth disease (FMD), an aphthous pathogenic disease, a pathogenic disease caused by a Picornavirus, scabby mouth (Orf), a pathogenic disease caused by a Parapoxvirus, and a pathogenic disease causing pox lesions)

Investment highlights

Unique Patented Technology

— Medi-Solfen® is a fast-acting topical analgesic, antiseptic and haemostat.

— Technology is secured by patents in USA, Australia, NZ, the EU and Canada, amongst others.

— The company has over 40 patents granted and registered globally protecting both animal and human applications.

— A new patent surrounding the newly developed manufacturing process was lodged in June 2021 and reviewed by IP Australia, as both novel and inventive, and has been lodged as a PTC in key global jurisdictions, extending the IP protection until 2041.

Significant addressable market

— The estimated global addressable market exceeds**$32.3**bn annually for wound care.

— Medi-Solfen® received strong interest from several commercial markets including USA and UK militaries.

— The USA military expressed interest for a 24-month project to investigate usage on “Military grade” wounds.

High Growth opportunity with Phase II trials

— First Patients Successfully Treated in Phase I Laceration Studies in Q1 2025. Conducted in Emergency Department (ED) and Phase I Unit, Kyiv, Ukraine.

— MHRA approved phase II Leg Ulcer study is planned to commence Q3 2026.

— Protherax UK has been appointed to undertake the reulatory pathway for both Phase II trials.

— The potential for both license milestones and royalty revenue are estimated to exceed $**27**m by 2031.

Commercialisation risks reduced

— Supporting evidence from the highly successful Tri-Solfen® product for animal use, and the recognition from global regulators, reduces the commercial risk for Medi-Solfen®.

— The active ingredients used in Medi-Solfen® are the same as the already commercialised animal product Tri-Solfen®.

— The active ingredients are readily used in human care, further reducing commercialisation risk.

— Demonstration of clinical efficacy is considered lower risk than standard pharmaceutical developments, as extensive proof of efficacy already exists.

— A clear regulatory pathway and well-developed plans exist for pivotal Phase II & III trials.

Registration & License Strategy Developed

— Distribution agreements are planned for negotiation through 2025 and 2026 via a similar arrangement that was achieved with Dechra PLC for the animal licenses.

— Tri-Solfen® (animal product) has been approved for use in Australia since 2012, NZ since 2018.

Note
Tri-Solfen® revenue from milestone and royalties for the Medical Ethics Group currently exceeds $37m (excluding equity capital raising from Dechra's 49% share purchase).

World leading specialists

— The research team is led by: Professor Keith Harding, Dr Chris Roberts, Professor Steve Jeffries, Dr Matthew Bayfield and Dr Meredith Sheil.

— The strong Executive and Advisory team, maintains a successful track record for developing, registering, and commercialising pharmaceutical products.

$6.2bn

Chronic wounds represent a significant burden in the UK

There are around 200,000 individuals in the UK at any time with a chronic wound. The cost to the NHS of caring for these patients is conservatively estimated at $4.9billion to $6.2billion per year (at 2005/06 prices).

The costs of skin breakdown and ulceration in the UK, Professor John Posnett Director of Health Economics, Smith & Nephew Advanced Wound Management, Hull and Professor Peter J Franks, Centre for Research & Implementation of Clinical Practice, Thames Valley University, London

3%

Venous leg ulcers

Venous Leg Ulcers (VLUs) are a major cause of morbidity and decreased health-related quality of life.[1] They have been reported to affect up to 3% of the adult population worldwide[1].

1. White JV, Ryjewski C. Chronic venous insufficiency. Perspect VascSurg Endovasc Ther2005;17:319 – 27.2. Margolis DJ, Bilker W, Santanna J, Baumgarten M. Venous leg ulcer: incidence and prevalence in the elderly. J Am Acad Dermatol2002;46:381 – 6.

3.7m

US surgical inpatient procedures

According to 2018 data from National Center for Health Statistics 3.7m visits to US emergency departments visits can be attributed to wounds, representing 3% of all visits annually[2].

2. National Center for Health Statistics, National Hospital Ambulatory Medical Care Survey, 2018.

Significant unmet need: A better solution for the treatment of chronic wound pain, leg ulcer pain and accidental wounds in humans.

Above:
Medi-Solfen® aims to reduce both the financial and personal costs relating to chronic wound care.

Economic pressure and challenges to prove efficacy in a world where populations and social burden is growing, means healthcare payors are increasingly asking for financial justification for treatments. Medi-Solfen® aims to reduce both the financial and personal costs relating to chronic wound care.

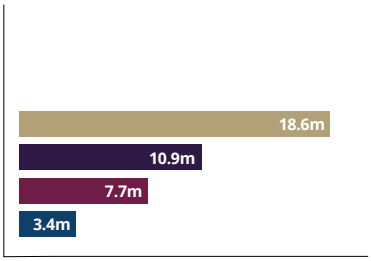
Pain and wound healing, the direct correlation

Patients living with a chronic wound are often subjected to dressing changes. Dressing removal is considered to be the most painful aspect of the dressing procedure, exacerbating the original wound.

This is particularly problematic where a dressing has stuck to the wound or removal of a dressing has torn the skin.

Pain during dressing changes can also be evoked by the debridement of slough and necrotic tissue, the application of antiseptics and the use of wound cleansing procedures.

Chronic wound care



Annual visits (millions)
Worldwide annual levels of resource use attributable to managing wounds

Practice nurse visits
Community nurse visits
GP visits
Hospital outpatient visits

BMJ: Health economic burden that wounds impose on the National Health Service in the UK

Above:
Patients with venous leg ulcers report pain to be the worst aspect of having an ulcer.

Medi-Solfen® has the potential to treat chronic wounds such as Leg Ulcers and Pressure Ulcers.

Chronic wounds affect millions of people globally, a number expected to rise significantly due to the increasing proportion of elderly patients living longer.

There are three main types of chronic wounds: Venous Leg Ulcers, Diabetic Foot Ulcers and Pressure Ulcers. The research team were initially focused on the development of our technology for the treatment of Venous Leg Ulcers, which represent 80% of all chronic ulcers.

Cleansing chronic wounds of local barriers, such as dead tissue, is known as debridement which is an essential process to facilitate efficient healing. It has been shown that faster, more complete healing is achieved with frequent debridement. However, this process is not well tolerated and patients will often ask clinicians to stop before the procedure is completed, or avoid the procedure altogether, due to the pain and discomfort.

Offering extended hours of pain relief, ensures patient comfort and tolerance of the procedure. This pain also extends beyond completion of the procedure. Chronic pain is highly complex, may extend over months or years, and has enormous implications for a patient's quality of life, causing decreased activities of daily living, sleep disturbance, reduced mobility and social withdrawal.

$23.7bn

Chronic wounds represent a signiffiicant burden in the US

Annual incremental per-patient and overall payer burden (2012USD) of venous leg ulcers (VLU) in the US[1].

1. Rice JB, Desai U, Cummings AK, Birnbaum HG, Skornicki M, Parsons N. Burden of venous leg ulcers in the United States. J Med Econ. 2014 May;17(5):347-56. doi: 10.3111/13696998.2014.903258. Epub 2014 Mar 24. PMID: 24625244.

3%

Venous Leg Ulcers

Leg ulcers (VLUs) are a major cause of morbidity and decreased health-related quality of life.[2] They have been reported to affect up to 3% of the adult population worldwide.

2. White JV, Ryjewski C. Chronic venous insufficiency. Perspect VascSurg Endovasc Ther2005;17:319 – 27.2. Margolis DJ, Bilker W, Santanna J, Baumgarten M. Venous legulcer: incidence and prevalence in the elderly. J Am Acad Dermatol2002;46:381 – 6.

It has been shown that when patients with leg ulcers feel an ease or absence of pain, they interpret it as a positive sign of wound healing, which can make them feel hopeful and optimistic.

Medi-Solfen's® biggest potential role is in first aid and accident and emergency because it is applied topically and works very quickly to reduce pain and fight infection.

Dr Matthew Bayfield

Acute wound care

Above:
Trauma wounds are often treated within busy Accident and Emergency Units and these patients may likely be in shock and acute pain.

Medi-Solfen® has the potential to treat traumatic wounds, often presented in busy emergency rooms, where time is critical and patient comfort is paramount.

Trauma wounds are heterogeneous, ranging from clean lacerations to dirty puncture wounds and/or abrasions. Moreover, trauma wounds can occur at any anatomical location on the body, may involve superficial and/or underlying tissues and may have additional complicating features.

Patients who suffer from trauma wounds are often treated in busy Accident and Emergency Units where they may likely be in shock and acute pain.

Typically, these types of injuries will be cleansed with water or saline and then closed primarily with either sutures, staples, glues or tape. To facilitate this, particularly where suturing occurs, the wounded area is anaesthetised with a local infiltration of lidocaine / adrenaline and/or other local anaesthetics (TAC).

It is of note however, that wound infiltration with lidocaine / adrenaline is known to sting immediately upon administration.

Moreover, the injection itself may stimulate pain and/or provide additional anxiety to the patient.

Medi-Solfen®, a rapidly acting topical anaesthetic may clinically benefit acute wound care, so that emergency treatment is not delayed.

Military battlefield wound care

Above:
The US Department of Defense is seeking a topical anaesthetic wound care agent to be used for frontline pain management of acute traumatic wounds.

The inclusion of cetrimide in the Medi-Solfen® formulation may provide clinical benefits in provision of antibacterial activity in the wound over and above washing with saline or water prior to wound closure.

Presently, with the level of small arms and fragment protection that is issued to UK Armed Forces, the survival rate following combat trauma is approximately 98%; however, there has been an increase in the number of extremities, groin, and facial wounds, as these are areas that are not as well shielded by individual combat armour.

The US Department of Defense (USDOD) is seeking a topical anaesthetic wound care agent to be used for frontline pain management of acute traumatic wounds. In 2020 they commissioned an independent scientific review by US Army Medical Research & Development Command (USAMRDC) to determine merits of undertaking a detailed project to study the utilisation of Medi-Solfen for treating combat wounds.

Peer Review Overall Evaluation of Medi-Solfen's merits rated the product as 1.6 (on a scale 1.0 highest to 5.0 lowest).

98%

Survival rate following combat trauma
The survival rate following combat trauma is approximately 98% in the UK Armed Forces however, there has been an increase in the number of wounds in areas that are not as well shielded by individual combat armour.

Medi-Solfen® has the potential to reduce the use of morphine in the battlefield environment and be very effective at reducing pain.

Lieutenant Colonel Steve Jeffery,
Consultant burns and plastic surgeon

Market opportunity filling a significant unmet need in wound care.

The Solfen-Tech® platform technology delivers to multiple, clear and distinct markets.

Target markets:
Human wound care and pain management

- Immediate wound treatment for emergency services, medical clinics and defense forces
- Chronic wound care (e.g., ulcers)
- Post-surgery wound care
- Future opportunity in over the counter first aid treatments

Current position

- ✓ Larger indication
- ✓ Phase II trials are ongoing
- ✓ Low-cost Phase III studies

4.12%

Global Wound Care Market is expected to grow at a CAGR of 4.12% over the forecast period to reach an estimated value of AUD 46.3 billion by 2030.

Grandview Research Woundcare Global Market Analysis 2020-2030

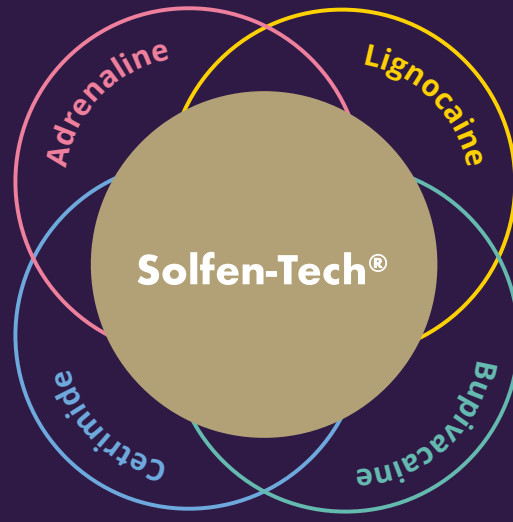
Utilising the technology to minimise wound pain in humans.

Presently, there is no commercially available product for humans that can be sprayed onto wounds in emergency situations to promptly alleviate pain, minimise bleeding, provide antisepsis and create a protective barrier.

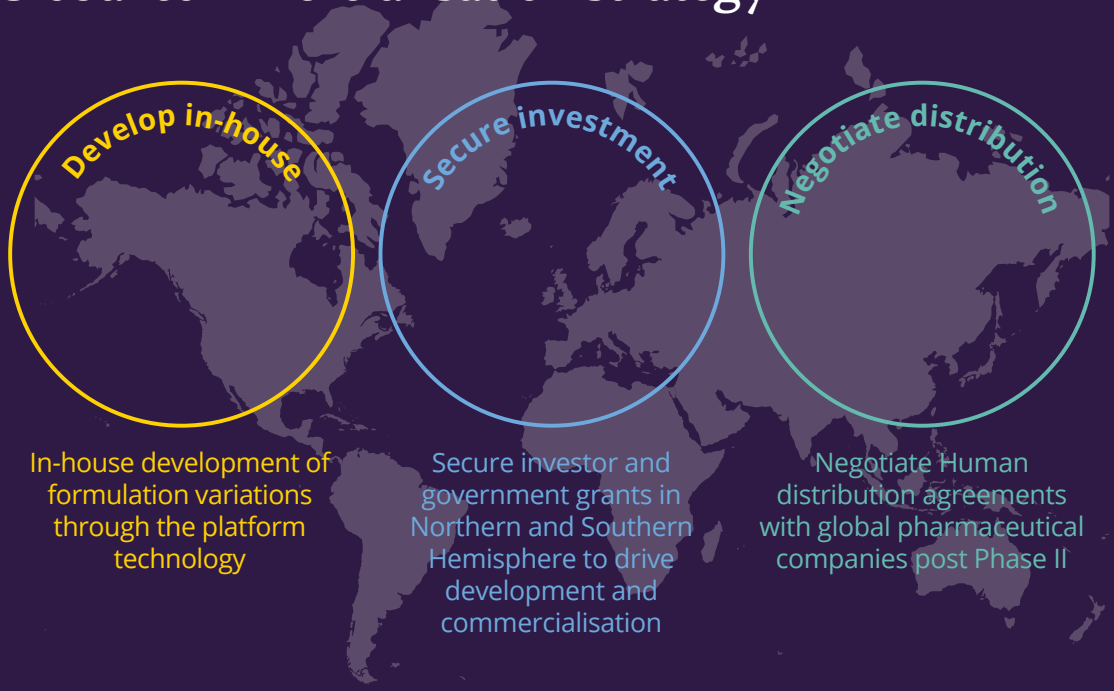
Solfen-Tech® is a patented combination technology platform for wound care and pain mitigation. The platform technology allows for multiple actives to be formulated together, held in solution, creating a stable viscous matrix, which enables spray and stay.

4
Proven active ingredients

1
Unique matrix



Global commercialisation strategy



In-house development of formulation variations through the platform technology

Secure investor and government grants in Northern and Southern Hemisphere to drive development and commercialisation

Negotiate Human distribution agreements with global pharmaceutical companies post Phase II

IP Protection
Our IP platform provides the opportunity to commercialise and develop unique, best-in-class products for a broad range of pain mitigation and wound care indications in livestock, companion animals and humans globally.

Partnering and business development
Partnering and business development is integral to our strategy of becoming a leader in wound care pain mitigation.

We have several strong and creative partnerships with innovative companies, contract manufacturing organisations and research institutions that have advanced, and continue to advance, our business.

Our technology
Medical Ethics has a proven platform technology and is focused on building a strong product portfolio within the field of wound care pain mitigation. Medical Ethics will consider out-licensing development and marketing rights to successful companies once key clinical milestones have been achieved.

To explore partnership opportunities, please contact our Business Development Team at:
BDM@medicalethics.me

Use of funds

Summary	Medi-Solfen Pty Ltd is the developer and owner of a spray and stay anaesthetic treatment providing pain relief in wound care for humans. The innovative, patented product utilises approved active ingredients allowing commencement of Phase II trials and a clearly defined regulatory approval pathway.	
Objective	Pre IPO – Raise $13 million to progress clinical trials and commercialisation objective of Medi-Solfen via a targeted IPO in 2026.	
Structure	Convertible Note	
Use of funds	R&D and registration costs	$6.3million
	Consultancy	$1.3 million
	General administration costs	$4.2 million
	Deal costs	$0.7 million
	IPO costs	$0.5 million
Proposed IPO	Up to $25 million raise to facilitate Phase III trials, registrations and commercialisation.	

Estimated R&D costs

AUD $m	Use
$2.2 – 2.7m	Phase III Leg Ulcer studies – Medi-Solfen_H_02
$10.9 - 12.3m	Phase III Leg Ulcer studies – Medi-Solfen_H_03
$2.9m	Phase II – Lacerations - Medi-Solfen_H_06
$19.8 - 21.6m	Phase III – Lacerations - Medi-Solfen_H_07 & Medi-Solfen_H_08
$1.9 – 2.4m	Phase II Post Op Pain Relief - Medi-Solfen_H_04
$4.7 – 5.5m	Phase III Post Op Pain Relief - Medi-Solfen_H_05
$6.3 – 7.1m	Studies as part of a Paediatric Plan – Medi-Solfen_Paed_01
$3.9 – 4.7m	Studies as part of a Paediatric Plan – Medi-Solfen_Paed_02

Recent scientific journals

International Wound Journal

"If these benefits are realised from a clinician and patient perspective for wound debridement as an initial indication, it could provide new horizons in pain management for a spectrum of wound-related procedures. Evidence from use in animal husbandry does support the concept that multimodal anaesthesia holds great potential in the field of wound management across many procedures."

Innovative pain management solutions in animals may provide improved wound pain reduction during debridement in humans, C. Roberts et al, Int Wound J, 2019.

Wounds UK

"As an example, there is growing evidence base, associated with the use of Tri-Solfen® in a variety of animal husbandry procedures, which provides excellent pain relief and could be considered for human clinical indications. By achieving early, effective and longer lasting pain relief will lead to optimising wound bed preparation. This could have potentially additional cost-saving benefits by reducing the overall healing time and the associated product and clinical resource usage costs."

Development of a UK cost analysis model for the various methods of debriding leg ulcers, C. Roberts et al, Wounds UK, 2019.

Swansea University

Research estimates the potential cost savings per year generated using Medi-Solfen® in treating Venous Leg Ulcers is:

£799,932 to £3,199,729 in Wales (or ~$1.6m - $6.2m AUD)

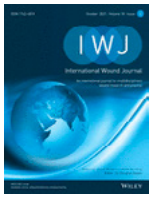
£17,300,882 to £69,203,530 in the UK (or ~$34m- $140m AUD

Determination of current standard care for management of patients with Venous Leg Ulcers, College of Human & Health Sciences, Swansea University 2018.

British Army

"It is envisaged that the availability of this product could allow for safe, fast acting and long-lasting pain relief in large numbers of casualties with blast-related burn injury, and / or have an opiate-sparing action. Deployed military personnel could be issued with a small, ruggedized canister containing the solution instead of / as well as the OTFC."

Professor Steven Jeffrey, Consultant Burns and Plastic Surgeon British Army medical unit.



Wounds UK

Prifysgol Abertawe
Swansea University

ARMY

USA Department of Defense

Details

US Department of Defense (USDOD) is seeking a topical anaesthetic wound care agent to be used for frontline pain management of acute traumatic wounds

In 2020 USDOD commissioned an independent scientific review by US Army Medical Research & Development Command (USAMRDC) to determine merits of undertaking a detailed project to study the utilisation of Medi- Solfen® for treating combat wounds.

Peer Review Overall Evaluation of Medi-Solfen's merits rated the product as 1.6 (on a scale 1.0 highest to 5.0 lowest).

The Summary Paper is available on request.

Outcomes of Peer Review

Key strengths noted by the peer review include:

"While the key focus is analgesia, the additional haemostasis and antimicrobial activities also strongly align to the research areas of interest."

"...given that they are beginning with a product that is already in successful and commercial comparable use (a farmyard could easily be compared to an austere forward location) is a plus."

"The intellectual property plan is appropriate, and the team has a history of success in translating their technology into a globally marketed product."

"As trauma and wounds are the leading cause of death and reasons to seek medical attention worldwide, the potential utility of such an "off-the-shelf" agent as proposed by the researchers to both the military and civilian populations would be of tremendous importance. The project clearly meets military goals and applications."

"The PI and other investigators involved are well versed in the agent and its testing. This is a very strong group."

> **"The potential for this technology to have a positive, beneficial impact on military medicine for both military and civilian injuries is tremendous."**
>
> US Army Medical Research & Development Command

Medi-Solfen Board


1.


2.


3.


4.

1. Allan Giffard

Co-Founder, Managing Director

Allan has a successful track record in the development and commercialisation of market leading products in animal nutrition, health, and welfare. He has extensive international experience in successfully negotiating license and distribution agreements with major pharmaceutical companies. He also has vast experience in developing and presenting improved animal welfare programmes and standards, as well as supply chain traceability for incorporation into global retailers CSR policies and their supply chain. Allan is a member of the Australian Institute of Directors and previously, an advisor to the Australian Wool Innovation, Landmark, Bayer Healthcare and Virbac Animal Health.

3. Charles Olsson

Co-Founder, Communication and Business Development Director

Charles has extensive experience in the Australian Agri business, including livestock nutrition and stock medicine manufacturing, sheep and wool production, and salt mining. He has been on various Agricultural industry boards, including directorships on Australian Wool Innovation, chairing marketing and IP divisions of Woolmark and AWI.

In addition, Charles has a Bachelor of Economics in Accounting from Macquarie University and he is a member of the Australian Institute of Company Directors.

Currently, he is the Managing Director of Four Seasons PTY LTD, a national livestock supplement company, supplying 400 rural retailers throughout Australia, as well as exporting to NZ and South East Asia.

2. Dr Meredith Sheil

Co-Founder, Chief Medical Officer

Meredith is a specialist paediatrician with clinical and medical research experience and is the inventor of Medical Ethics' lead product, Tri-Solfen®. Her 30 years of experience includes paediatric accident and emergency, paediatric post-operative cardiac intensive care, wound management and mitigation of pain and inflammation. She holds a MBBS and PhD from Sydney University Department of Paediatrics and Child Health and is a Fellow of the Royal Australasian College of Physicians.

In addition, Meredith has over 18 years of experience in primary production, animal husbandry, wool and sheep meat production, land care and management. A graduate of the Australian Institute of Directors, she has a strong background in corporate and research governance as an Executive Director of the Australian Wool Innovation, Chair Science and Welfare Committee, and The Woolmark Company. She is a past local government councillor, Deputy Mayor and Chair of the Conservation Committee Hunters Hill Council in New South Wales, Australia.

4. Giles Coley

International Group Director for Dehra Pharmaceuticals Plc.

Giles joined Dechra in January 1999 as sales and marketing manager for Arnolds Veterinary Products, having previously spent 14 years primarily involved in dairy farming business consultancy.

During his time at Dechra he has been responsible for the launch and market development of a number of key brands, including Vetoryl.

Advisory Board

Professor Keith Harding CBE
Human Wound and Research Advisor

— First Director of the Wound Healing Research Unit Cardiff University 1991

— 2019-2013 Director of TIME Institute Dean of Clinical Innovation at Cardiff University

— Chair of the International Working Group on Wound Healing in Diabetic Foot Disease

— Clinical practice exclusively focused on treating patients with wound healing problems

— Director of the A star Institute Singapore

— Authored over 350 publications on wound care

Dr Chris Roberts
Human Wound and Regulatory Advisor

— 20 years line management experience of heading clinical research and statistics teams

— Previous global head of Smith & Nephew clinical support & market development

— Key member of the Acquisition Team within Smith & Nephew medical and wound healing portfolio

— Managed global clinical Phase II and III programs in the management of Venous and Pressure Ulcers

— Recognised expert in Wound Healing in industrial, academic, and clinical settings

Lieutenant Colonel Professor Steven Jeffery
Medical Specialist Advisor

— 20 years of experience in military plastic surgery

— 2011 awarded the Military Civilian Partnership Award for 'Regular of the Year', as well as receiving the Wounds UK 'Key Contribution' award and the Smith and Nephew 'Customer Pioneer of the Year' award

— Awarded Fellowship of the Royal College of Surgeons of England ad eundem

— Expert adviser to NICE Medical Technologies Evaluation Programme

— Co-founded the Woundcare 4 Heroes charity, which is already making a big difference to the wound care of both serving and veteran personnel

Dr Matthew Bayfield
Cardiothoracic Surgeon

— Member of the Special Committee Investigating Deaths associated with Anaesthesia (1999)

— Head of Cardiothoracic Surgery at Strathfield Private Hospital (1999) and the Royal Prince Alfred Hospital (2005) Fellow of the Royal Australasian

— College of Surgeons (General Surgery, 1992 and Cardiothoracic Surgery,1995)

Peter Bishop
Corporate Advisor – HLB Chessboard

— Managing Director of HLB Chessboard specialising in advice regarding: Mergers & Acquisitions, IPO's & placements, debt structuring, valuation & share price

— Wealth of experience in private equity, agribusiness, health, and services

— Regularly acts as lead adviser to boards through corporate transactions and serves on the board of trustees for the Clem Jones Centre

— Previously sat on the UQDI Advisory Board, chairman of the UQDI Foundation Board and the JDRF state committee

Professor Peter Windsor
Veterinarian Research Advisor

— Emeritus Professor Sydney University

— Registered Specialist Veterinary Surgeon NSW

— PHD 1988 (UoS conferred April)

— Diplomate, European College of Small Ruminant Health Management

Commercial highlights

1st & only

First and only bio-compatible combination wound care for farm animals approved by a major regulator

2018

2018 Bayer Animal Health appointed marketing partner for NZ

40+ patents

Over 40 global patents granted covering all species (including humans) in the USA, EU, Canada, NZ and Australia

2007

2007 Licensed to Bayer Animal Health

$31m

2022 Dechra PLC Secured ANZ rights for animals in 2022 for $31m increase shareholding to 49.5%

1st

International animal registrations commenced first dossier lodged in the EU June 2018 FDA Q12022

33%

2017 Dechra Pharmaceuticals a FTSE 100 company purchased a 33% stake in the parent company Medical Ethics

>$60m

> $60m in retail sales since launch

No.1

Selected by the Australian Government RDC and livestock industries as the number 1 priority for registration for all livestock in Australia

200m+

Proven market acceptance 200 million + animals treated 80% +, market penetration for livestock in Australia

Phase Ib

First patients successfully treated in Phase Ib Laceration Studies in Q1 2025. Conducted in Emergency Department (ED) and Phase I Unit, Kyiv, Ukraine

Successful

Successful applications for NADA and SME status in the USA and EU (fee reductions approved)

Effective

Recognized by Temple Grandin (Colorado State University) and other global animal welfare scientists as the most practical & effective option to address wound and pain management in livestock

Funded

Successful research collaborations funded by Australian and Canadian governments with Sydney, Lisbon (Portugal), Padua (Italy), universities and Australian livestock industries

2042

New Manufacturing Patent lodged in 2022 and recognised by IP Australia as both novel and inventive, providing protection until 2042

Over 30

Over 30 peer reviewed studies confirming safety & efcacy in several animal species and indications published in prestigious international science journals e.g., American Journal of Animal Science

The best

Voted best global farm animal product for 2016 by leading animal industry Animalpharm magazine

ARENSIA
EXPLORATORY MEDICINE

ARDENA

Pharmaxis

ProTherax LTD
Regulatory/Technical Writing

Dechra

Summary

Unique

Medi-Solfen® presents a unique platform technology, Solfen-Tech®, which enables the formulation of multiple active ingredients together, creating a stable viscous matrix held in solution, providing effective spray and stay functionality.

Patent protected

The company holds valuable commercial rights to more than 40 patents in key global markets, with additional patents pending, ensuring protection until 2041.

Unmet need

Independent research has highlighted the crucial role pain mitigation plays in the wound healing process. Medi-Solfen® stands out as there are no similar combination wound care agents available topically for the first-line treatment of open wounds and pain management.

Patient focussed

Medi-Solfen® places a strong focus on patient well-being, contributing to an improved standard of care. Unlike the current standard, which involves injectables performed only by trained medical staff, Medi-Solfen® offers fast onset of action, relieving pain, controlling bleeding, and providing a protective film over the wound to promote healing.

Accelerated

The product's development has been accelerated to Phase II due to the utilization of well-established active ingredients and demonstrated efficacy in veterinary indications. This progress positions Medi-Solfen® as a promising solution in the field of wound care and pain management.

Designed and produced by:
www.thinkerdoer.com

thinker/doer

Medi-Solfen

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