Corporate Presentation

March 2015

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About Avita Medical - Company Overview

- **Unique Regenerative Family of Products for treatment of a wide array of skin defects**
  - reCELL® - Spray-on Skin® for acute wounds
  - regENERCELL - for chronic wounds
  - reNOVACELL - for aesthetic/plastics
- **Lead product ReCell® Spray-On Skin ® launched in Europe (CE Marked), Australia (TGA), China (SFDA)**
- **Legacy respiratory products source of recurring revenues**
- **Dual Listing**
  - **Australian Exchange (ASX:AVH)**
  - **US ADR Listing (OTCQX:AVMXY)**

Galatéa de las esferas Salvador Dalí, 1952

Developing An Elegant Solution for Skin Defects

- **Novel autologous skin regeneration therapy can be used to treat diverse patient populations**

- **Regen family of products already approved and marketed in multiple countries WW providing**
  - Growing revenue stream (sales up 21% FY2013-FY2014)
  - Leveraging market approvals to validate commercial models
  - Post-marketing clinical data to bolster confidence in the technology

- **Ongoing Development Effort**
  - First indication for **ReCell** in the **US** will be acute burns
    - Phase III clinical trial in burns is underway; initial results in 2H2016
      - Larger burns comprising 5-50% of total body surface represent an area of little clinical innovation with mesh grafts being the standard of care; **ReCell solves a clear unmet medical need**
  - Follow-on indication opens up **ReGenerCell** opportunity to the vast market of chronic wounds
    - Chronic venous leg ulcers (VLU): Randomized pilot (N=65) ongoing in EU, results 2H2015
    - Diabetic foot ulcers (DFU) represents next opportunity—Int'l feasibility trial results 2H2015
  - **ReNovaCell** confirmatory ex-US trials in scars/aesthetics/repigmentation ongoing

- **Technology platform is an autologous cell harvesting device; IDE studies and FDA PMA process present lower barrier to entry than BLA/IND**

- **Corporate partnerships across all indications to drive next phase of commercial strategy**

Technology Overview:
The Platform & What It Can Do For Patients

What is Our Regenerative Platform?

- **ReCell is an autologous cell harvesting device that is made up of:**
  - a proprietary enzyme formulation,
  - a processing unit comprised of sterile enzyme soak-, buffer rinse- and filtering- chambers and a sterile tray for mechanical disaggregation of the skin sample
  - a validated set of applicators designed to overlay the wound area with a suspension of healthy cells
- **ReCell allows rapid (30 min) creation of a regenerative epithelial suspension, comprised of:**
  - autologous skin cells (keratinocytes, fibroblasts, melanocytes) and
  - signaling factors (cytokines, chaperones like hsp90, growth factors)
- **Cells in the autologous suspension are disaggregated, free of neighbor cells and not contact inhibited (free-edge effect)**
- **Jumpstart regenerative healing upon application to wound**

Wood et al. 2012. *Burns* 38:44.
Singer & Clark. 1999. NEJM. 341 (10): 738.

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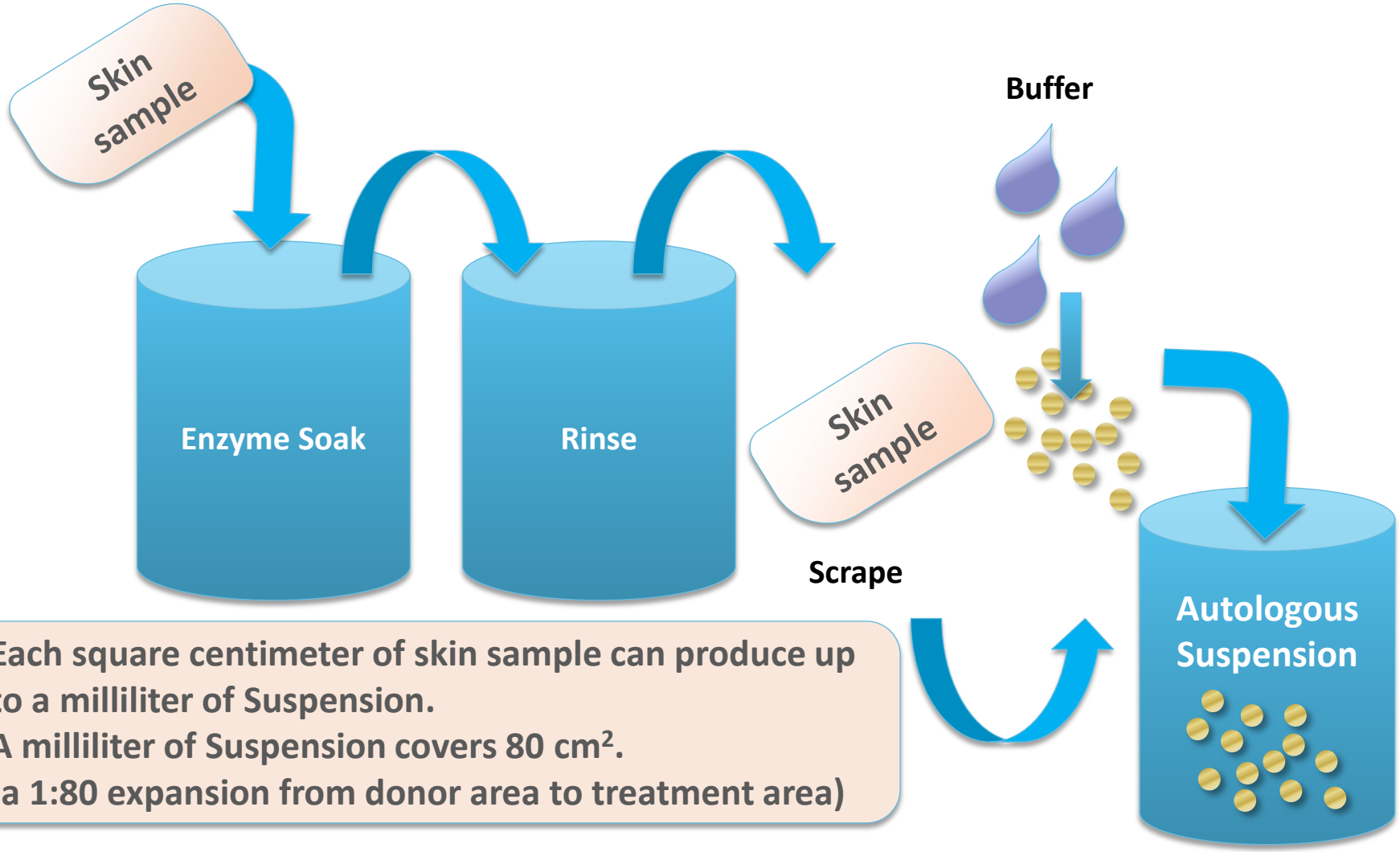
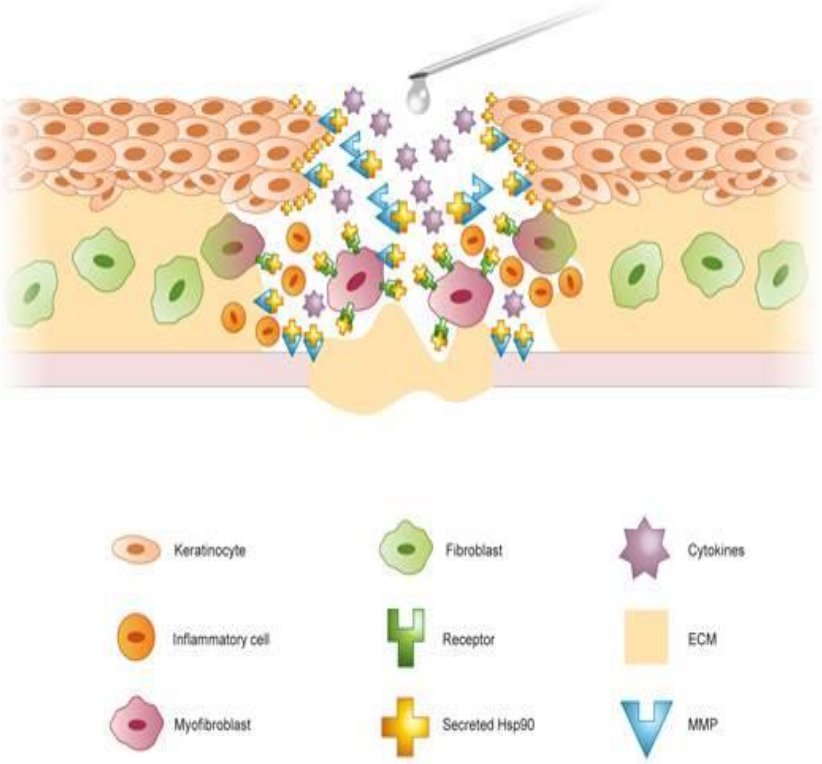
Schematic of Autologous Suspension Prep



Each square centimeter of skin sample can produce up to a milliliter of Suspension.
A milliliter of Suspension covers 80 cm^2.
(a 1:80 expansion from donor area to treatment area)

~30 minutes

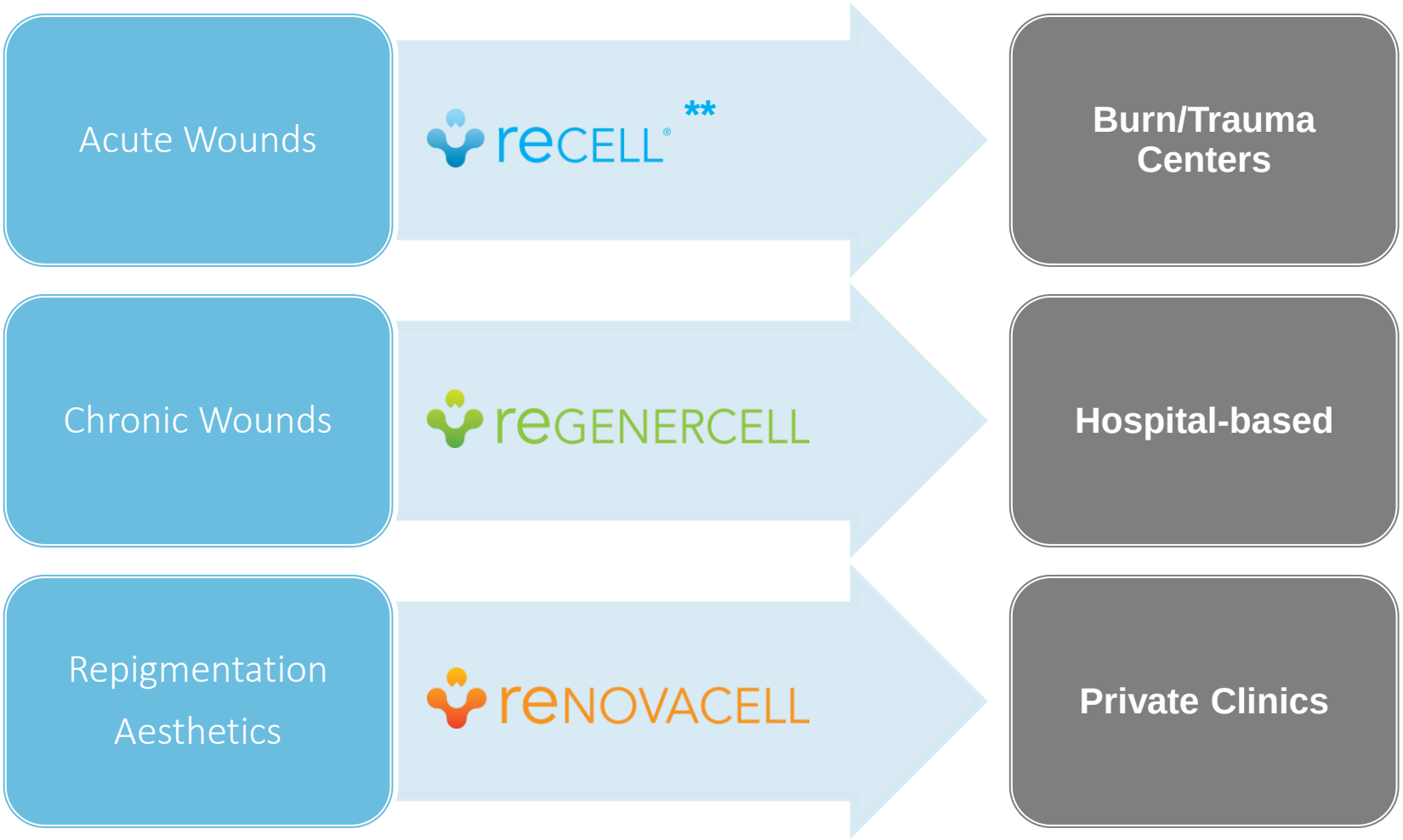
Rationale for Use of Autologous Suspension in Wound Healing



- Patient-specific autologous samples derived from healthy areas of the skin contain a complete mix of all skin cells and factors and can "jump start" the wound healing process
- Autologous cells can survive well in a hostile wound environment
- Being cells in suspension, devoid of attached neighbour cells, these are highly proliferative "free edge" cells without contact inhibition seen in sheets or grafts of cells

Velander et al. 2009. *J Surg Res*. 157: 14.
Li et al. 2007. *EMBO J.* 26: 1221.
Cheng et al. 2008. *Mol. Cell Biol.* 28: 3344.
Woodley et al. 2009. *J Cell Sci.* 122: 1495.
Singer & Clark. 1999. NEJM. 341 (10): 738.

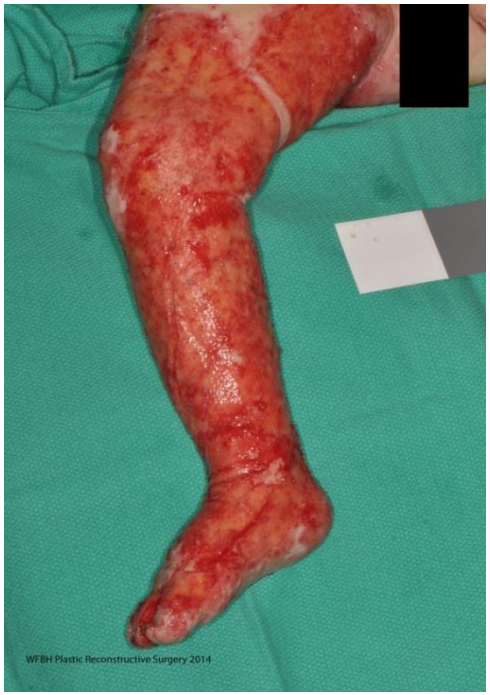
Indication Specific Agents in the Regenerative Platform



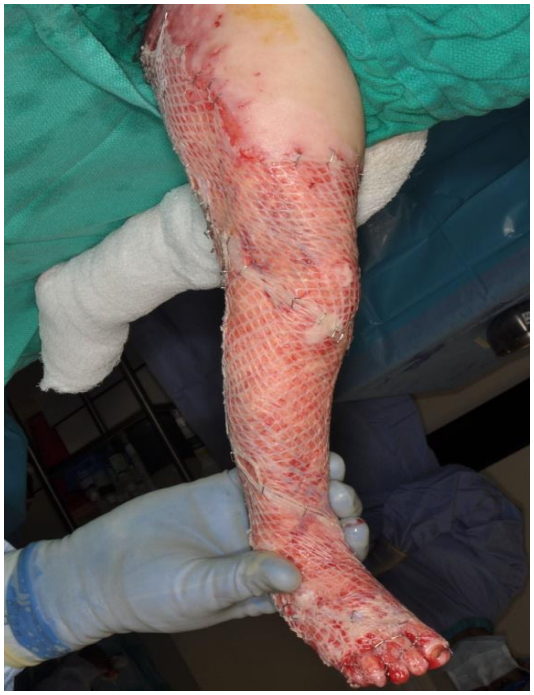
- Starting in 2014 -ReCell, ReGenerCell and ReNovaCell are all room temperature stable products
- ** Launch of High Capacity ReCell for treatment of up to 1920 cm^2 of body area

ReCell Therapy in Combo with Mesh Graft: Evolving Standard of Care for Full Thickness Burn Injury

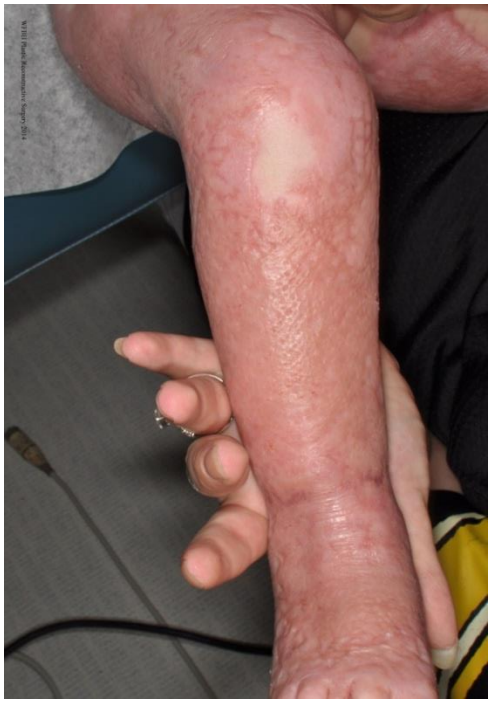
- Treatment of large surface/deep burns with limited donor site usage—unmet need in burn care
- ReCell (combo with mesh graft) designed for clinical efficacy with minimal donor site requirement
- Basis of NICE recommendation for ReCell research; design of the US pivotal trial



Pre-treatment
Excised 3rd degree burn



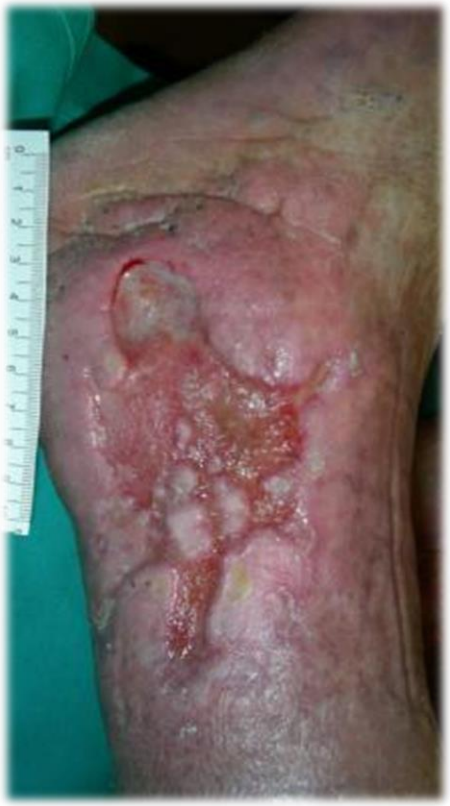
Treatment
ReCell + Mesh Graft



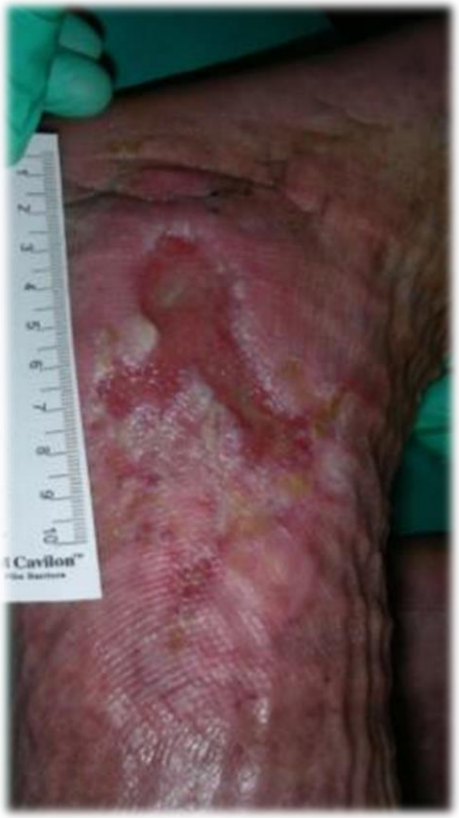
Week 14 post treatment

ReGenerCell Therapy Can Achieve the Unmet Need of Complete Wound Closure for Chronic Ulcers

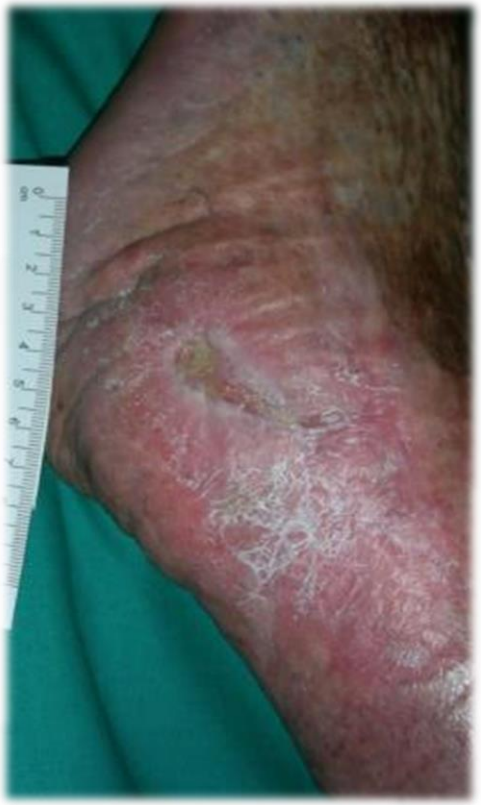
Case Study: 84 yr old male with controlled high BP, colon cancer in remission, chronic venous insufficiency. Left ankle VLU open 7 yrs treated with ReGenerCell.



Baseline
VLU area = **55cm²**
ReGenerCell Treatment



Week 7
VLU area = **8cm²**
% Re-epithelialization vs baseline= 85%



Week 20 (5 mo)
VLU area = **2cm²**
% Re-epithelialization vs baseline= 96%

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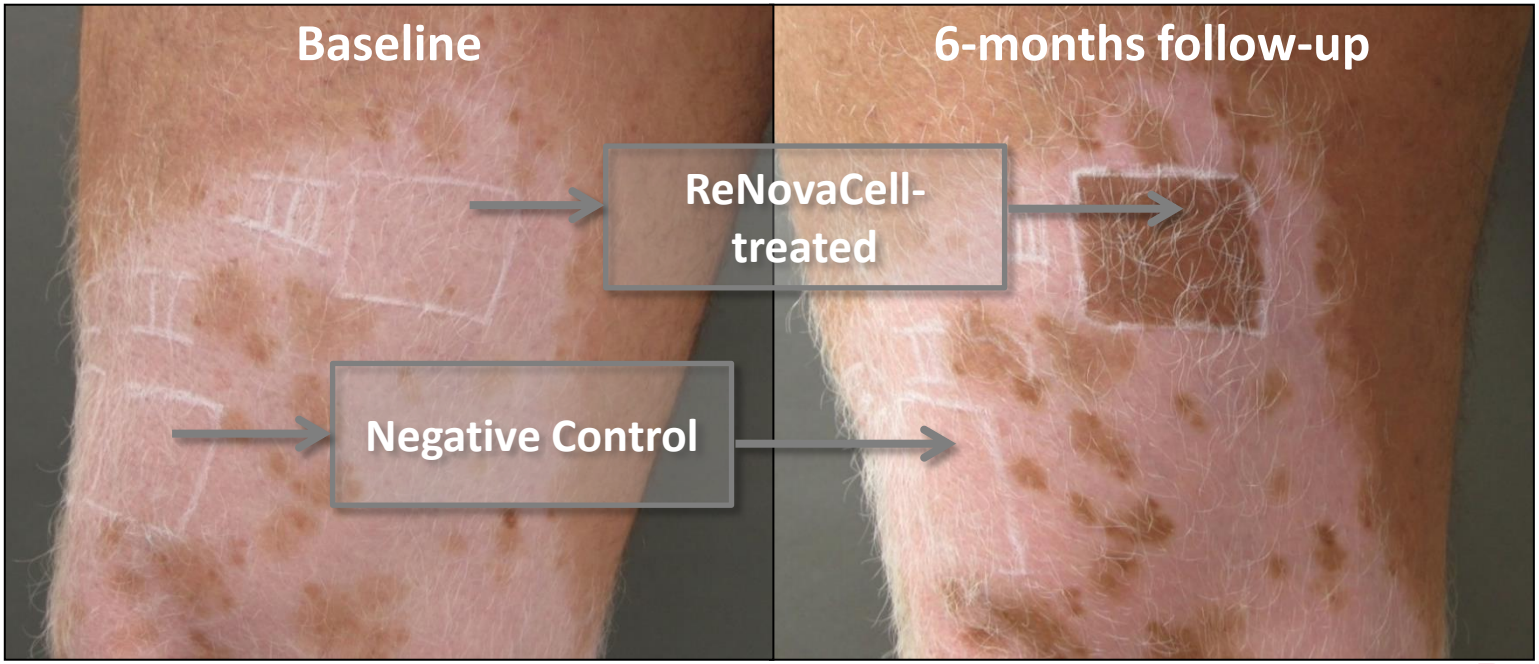
ReNovaCell: Simple Solution for Skin Repigmentation

- Re-pigmentation of hypo-pigmented skin due to old age, injury, skin treatments, vitiligo– is the unmet medical need in aesthetic dermatology
- Nonsurgical options “lotions & potions” and light therapy is sometimes efficacious
- Melanocyte transfer is the sole surgical choice for repigmentation but expensive, time consuming
- ReNovaCell is the only simplified, cost-effective solution for skin re-pigmentation with rapid results (1-6 months)

Case Study: patient with segmental vitiligo (duration > 5yrs)



The Opportunity:
Market Size & Dynamics

Market Opportunity

Selected Indications e.g., excludes plastic and maxillofacial surgeries		Opportunity				Market Size (assume 1 device@$1000/patient ASP)
		US *pop. 316M* (11.4% diabetes[1])	**UK, FR, DE, IT** *pop. 271M* (8% diabetes, avg[1])	**Aus** *pop. 23M* (5.1% diabetes[1])	**China** *pop. 1.4B* (9.3% diabetes[1])	
Chronic Ulcers	DFU[2]	9.0M	5.5M	0.3M	31.6M	**$46.4B**
	VLU[3]	3.2M	2.7M	0.2M	13.6M	**$19.7B**
Burns annual admissions		40K[4]	42K[5]	8.6K[6]	3.4M[7]	**$3.5B**
Aesthetics annual procedures[8]		1.7M	585K	117K	157K	**$2.6B**
Vitiligo *0.1% to 2% of pop.*[9]		316K	271K	23K	1.4M	**$2.0B**
TOTAL*		**$14.3B**	**$9.1B**	**$0.7B**	**$50.1B**	***>$70B***

1 International Diabetes Federation (IDF) Diabetes Atlas, Sixth Edition (2014)
2 [Lifetime incidence: 25% of diabetics] Singh et al. "Preventing foot ulcers in patients with diabetes." JAMA 293, no. 2 (2005): 217.
3 [Prevalence*: 1% of pop.*] Humphreys et al."Management of mixed arterial and venous leg ulcers." *Br. J. Surg.*94, no. 9 (2007): 1104.
4 American Burn Association 2013 Fact Sheet (www.ameriburn.org)
5 Brusselaers et al. "Severe burn injury in Europe: a systematic review of the incidence, etiology, morbidity, and mortality." Crit Care 14 (5) (2010): R188.
6 Australian hospital statistics. Australian Institute of Health and Welfare. (2012)
7 Peck MD. Epidemiology of burn injuries globally www.uptodate.com
8 ISAPS 2013 International Survey on Aesthetic/Cosmetic Procedures Performed (dermabrasion, resurfacing, facial rejuvenation, botulinim toxin)
9 Alkhateeb A, Fain PR, Thody A, Bennett DC, Spritz RA. "Epidemiology of vitiligo and associated autoimmune diseases in Caucasian probands and their families." Pigment Cell Research 16, no. 3 (2003): 208-214.

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Addressable Patient Populations within Skin Defects

Acute Burns/Trauma

Small but defined market

Build sales of ReCell in EU, AUS, China, RoW

Progress US FDA trials (burns and other applications)

Chronic Wounds (VLU & DFU*)

Large, defined yet untapped market

Advance clinical trials in VLU based on results from ongoing pilot trial

Initiate follow on program in DFU

Aesthetics/ Repigmentation (incld. Vitiligo)

Progress aesthetic clinical development for large, lucrative marketplace

Vitiligo is a large market but poses educational burden

* VLU= venous leg ulcer; DFU= diabetic foot ulcers

Company History:
Turnaround Story Anchored By An Elegant Technology Platform

Historical Challenges With the Regenerative Platform

- **C3 run clinical development of ReCell was *ad-hoc*; based on case series for AU, EU approvals, thus undermining:**
  - **KOL* acceptance/uptake:** no prospective randomized clinical trials to demonstrate efficacy
  - **Salient positioning for unmet need:** resulting in poor early adoption of the product
  - **Optimal device design:** current ReCell device limited to small burns (2% body surface)—which is not an unmet need, nor cost-effective
  - **US clinical trials:** previous phase III attempt was flawed—in hindsight, poor choice of comparator and enrollment criteria, limited clinical relevance
  - **Characterization of ReCell biology:** without phase I/II/III development, ReCell MOA* was poorly understood, creating myths in the marketplace
    - ReCell device harvests more than just skin progenitor cells (from the dermal-epidermal junction)
    - ReCell is not just an epidermal cell suspension – critically important fibroblasts are also present
    - ReCell does not require donor and recipient site-matching for proper repigmentation
- **C3 sought approvals to market one product, ReCell, across multiple indications–thus undermining:**
  - **MOA*:** Different aspects of the platform technology's MOA are key to different indications
  - **Key messaging:** Must vary with indication and associated unique unmet medical need
  - **Partnering:** Commercial partner targeting can vary by indication; a single brand ReCell is restrictive to indication-specific partnering

* KOL= key opinion leaders, MOA= mechanism of action; SOC= standard of care

The Turnaround: New Mandate, New Management

New Mandate:

1. Creating an indication-specific value proposition and branding for the regenerative platform **(2014-2015)**
2. Restart US clinical trial in burns with expanded enrollment criteria reflecting current unmet need and SOC **(2015)**
3. Launch new (expanded) device in ex-US territories for treatment of areas up to 1920 cm^2 **(2014-2015)**
4. Focus on larger marketplace opportunities: chronic wounds, aesthetics **(2014 onwards)**
5. Prioritize business development for indication-specific commercial partnering **(2015 onwards)**

New Management:

Timothy Rooney, CEO: 20 years senior finance and operations management; pharmaceutical wholesale distribution and medical device industries.

Andrew Quick, VP Research & Technology: 21 years medical device experience; expertise in design, development and clinical research.

William Marshall, VP Operations: 31 years industry experience; expertise in lean manufacturing, quality and regulatory systems.

Lorraine Glover, General Manager, Asia Pacific: 22 years experience in the commercial biotechnology and medical devices industry

Claire Darby, General Manager, EMEA: 10 years of experience in medical device and regenerative medicine

Justin McCann, VP Finance: 20 years of finance experience in the tech and biotech sectors

Advisory Team

Board of Directors

Lou Panaccio, BOD chair: 30 years of executive leadership experience in the life sciences and health services, including 15 years board-level experience. He is currently a Non-Executive Director of one of the world's largest medical diagnostics companies, ASX50-listed Sonic Healthcare Limited (SHL). In addition, Mr Panaccio is also the Executive Chairman of Genera Biosystems Limited (GBI).

Ian Macpherson: 25 years of advisory expertise including financial director at VisioMed– one of the parent companies of Avita Medical. Mr Macpherson advises on capital structuring, equity and debt raising, ASIC and Securities Exchange compliance procedures.

Professor Fiona Wood, AM: Professor Wood is the inventor of the ReCell technology and currently Director of the Western Australian Burns Service and a Consultant Plastic Surgeon at both the Royal Perth and Princess Margaret hospitals in Perth. She is the Chairman of the Fiona Wood Foundation (formerly the McComb Research Foundation) and was named as Australian of the Year in 2005.

Jeremy Curnock-Cook: a veteran investment manager specializing in biotech drug discovery sector; Mr. Curnock Cook is currently on a number of boards of international healthcare and biotechnology companies and is the former head of the life science private equity team at Rothschild Asset Management.

Matt McNamara: over 25 years of healthcare & medical sciences experience; 11 years in Sales & Marketing and General Management with MRK and JNJ. He has served as SVP Business Development for eBioinformatics Inc., and was CEO of a Life Sciences Venture Capital fund, SciCapital Pty. Ltd.

Dr. Michael Perry, DVM, PhD: 20+ years of cell therapy experience including senior global head of stem cell therapy at NVS and global head of R&D at BAX. Dr. Perry has been a CEO and board member of several US biotech cell therapy companies.

The Path Ahead:
Clinical Trials Results And Commercial Strategy

Clinical And Commercial Milestone Provide Value Drivers—Two Year* Outlook

- **Acute Burns:**
  - Start of US phase III pivotal trial CTP001-6 — 1Q2015
  - Initial clinical results from US phase III trial — 4Q2016
  - PMA submission to the FDA for acute burns — YE2016
  - US approval of ReCell for acute burns — 3Q2017
  - Improved EU ReCell reimbursement — 2015-2016
  - Commercial Partnership(s) — 2016-2017
- **Chronic Wounds:**
  - Results from randomized controlled pilot trial in VLU — 3Q2015
  - Label expansion in Australia for VLU — 4Q2015
  - US IDE submission for VLU — 2Q2016
  - Initiation of US pivotal trial in VLU — 4Q2016
  - Completion of Int'l feasibility study in DFU — 2H2015
  - Commercial Partnership(s) — 2016-2017
- **Repigmentation/aesthetics:**
  - Randomized controlled trials lead to EU launch — 1Q2015
  - Label expansion for repigmentation in Australia — 3Q2015, 4Q2015
  - Commercial Partnership(s) — 2016-2017

*calendar year

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US IDE Approval Experience (CTP001-6)

Aim: Evaluation of the efficacy of ReCell in combination with meshed skin graft for the treatment of all acute burn injuries

CTP001-6

- Sample Size: 25
- Target enrollment (N): 30
- **Age: ≥5yrs**
- **All burns requiring skin grafts (2nd & 3rd degree)**
- **Treatment area: 300+ cm^2 /area**
- **% Burn: 5-50% TBSA**
- Centers: 4-6

Qualifying burn area bisected to randomize 1:1 for each patient

ReCell autologous suspension in combination with protocol defined wider mesh graft

Conventional skin graft

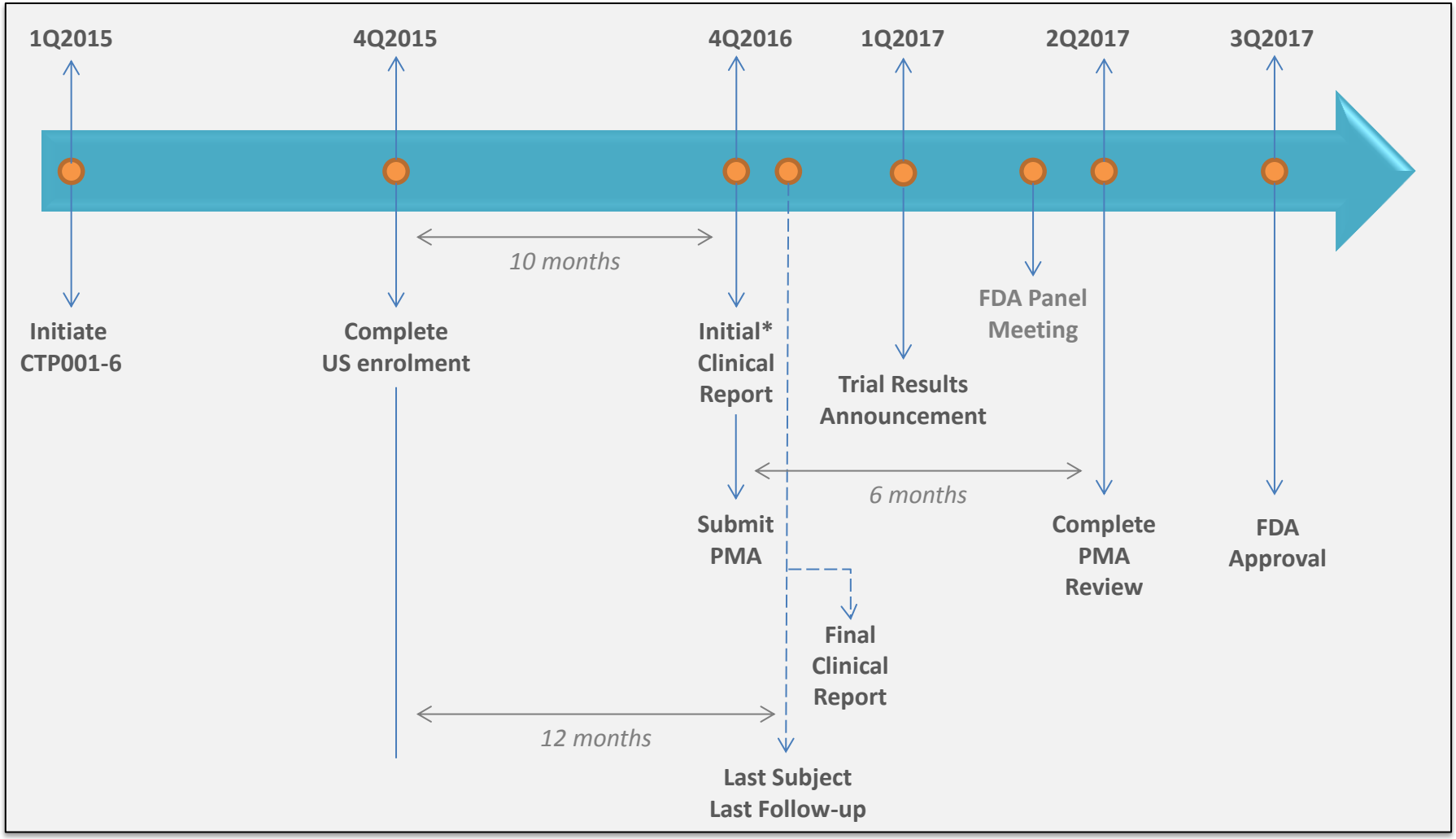
Endpoints & Assumptions:

1. **Incidence of complete closure rate of recipient site at 8 weeks***: Non-inferiority of ReCell/Mesh combo versus graft alone
2. **Expansion ratio at time of treatment**: Superiority** of ReCell/Mesh combo versus graft alone

- **Less stringent inclusion/exclusion criteria will allow faster enrolment**
- **More objective primary endpoints will reduce variability and allow smaller sample size**
- **"Real world" use of ReCell/mesh graft combo will allow broad label and extensive use**

* Additional procedures aiding wound closure allowed within initial 8 weeks; ** ReCell expansion ratio: control expansion >1

US ReCell Burns Approval Timeline



*Complete effectiveness data
& interim (9-month) safety data

Key Developments In EU/RoW Reimbursement Strategy For ReCell

United Kingdom

- **NICE commissioning research to verify the value proposition of ReCell in combination with mesh graft; additional data from CTP001-6 will also be submitted for updated guidance**

Germany

- **Supporting application submitted by eight hospitals, multiple authorities involved including:**
  - InEK: Institute for the Hospital Remuneration System
  - DIMDI: German Institute of Medical Documentation and Information
  - G-DRG: Diagnosis Related Group; ICD-10-GM 'German Modification'

Turkey

- **ReCell has been classified with a code and placed on the 'positive list' for temporary reimbursement until permanent status can be achieved.**

Australia, France and Italy

- **Process is underway**
- **Sales of ReCell have been up 58% YoY in EU (ex-UK) and 25% in AU despite absence of formal reimbursement structure**

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NICE: National Institute for Health And Care Excellence (UK)

Commercial Strategy Involves Partnering

- **2015 will be a watershed for the company; clinical strategy and approval in place**
  - Ex-US approval/launch of newly branded products
  - US initiation of phase III trial in burns; RCT trials in VLU ongoing
- **Commercial strategy thru corporate partnerships is the next focus; near term catalyst**
  - Strategic deals by indication/call point/geography

regENERCELL

reNOVACELL

reCELL®

AVH: "To do" list

- **Secure Approvals**
- **Deliver Product**
- **Build Evidence Base**
- **Demonstrate proof of concept commercial success** ***(model market: EU)***

illustration purposes only

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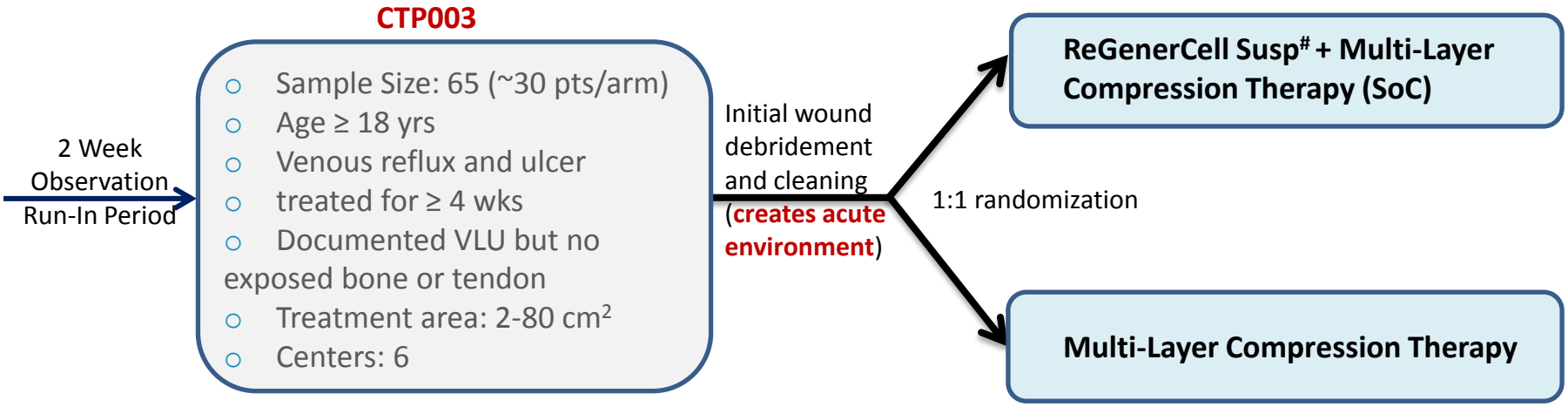
Pilot Trial for ReGenerCell in Venous Leg Ulcers (CTP003)

Aim: Evaluation of the efficacy of ReGenerCell in combination with standard compression device Versus standard of care for the closure of venous leg ulcers (VLU)



Endpoints:

1. **Incidence of ulcer closure* at 12 weeks post randomization**: Assumes superiority of ReGenerCell over SoC
2. Patient reported pain & quality of life
3. Treatment cost differential between ReGenerCell and control
4. Adverse event profile; safety of ReGenerCell in VLU

TRIAL STATUS: Trial initiated 3Q2013; final results 3Q15

ReGenerCell patients are eligible for repeat ReGenerCell therapy at study week 6-7 if the extent of wound epithelialization is < 85% but > 15%

* Ulcer closure is defined as complete re-epithelialization without drainage

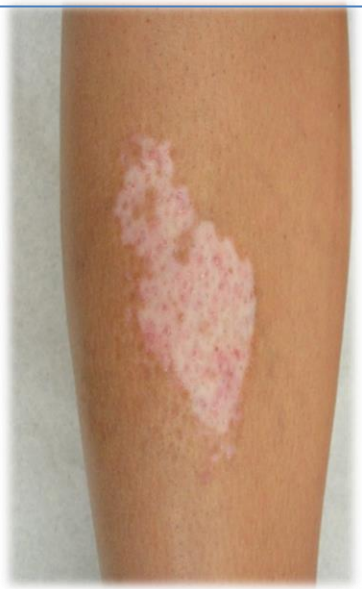
US Market Entry Timelines for VLU

Description	Target Date
Complete VLU pilot trial enrolment	1Q2015
VLU pilot trial results	**3Q2015**
Use pilot trial results in VLU for label expansion in Australia	**4Q2015**
Begin planning the pivotal US VLU trial for IDE submission	2015
Pre-IDE meeting with FDA	YE2015
Submit IDE application to FDA/ application acceptance	2Q2016
Commence pivotal US VLU clinical trial	4Q2016
Report pivotal US VLU trial results	**Mid-2019**
FDA PMA submission for VLU	YE2019
FDA approval of ReCell/ReGenerCell in VLU	2Q2020
US Launch in VLU	**3Q2020**

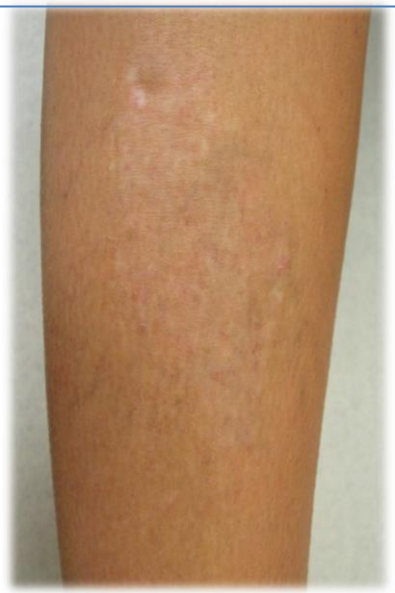
ReNovaCell In Aesthetics & Repigmentation

- In the early 2000's Avita Sponsored PSR-01 and PSR-02 studies first demonstrated proof of ReCell (now, ReNovaCell) efficacy in scars revision and repigmentation;
- Two recently completed randomized trials with objective measures of repigmentation demonstrate statistically significant benefit with ReNovaCell vs controls
- Together they provide a sufficient proof of efficacy and launch of ReNovaCell in ex-US territories
  - **EU CE-Mark: 1Q2015** **AUS (TGA): 3Q2015** **China (sFDA): YE2015**
- US clinical strategy for ReNovaCell in Aesthetics under review; US commercial strategy based on partnering

Case Study: ReNovaCell for Vitiligo



Pre-treatment



18 wks post treatment

Courtesy of L Komen & A Wolkerstorfer; Netherlands Institute for Pigmentation Disorders

Conclusion:
Next Steps For Continued Growth

Today's Avita: Well-Positioned for Growth

- **Transformative regenerative medicine platform efficacious across multiple skin defects**
  1. Clear US strategy for FDA approval for acute burns- initial indication for US market entry
  2. Ex-US launch of ReCell is gaining momentum (ReCell sales up 21% YoY)
  3. Ex-US reimbursement strategy for ReCell is a priority
  4. Expanding Sales & Marketing / Business Development team
  5. Rebranding the regenerative franchise into indication specific products (ReCell, ReGenerCell, ReNovaCell)
  6. Clear path to market for chronic wounds (VLU, DFU)
     i. Ex-US label expansion upon completion of pilot VLU study in 3Q15
     ii. US pivotal trial for VLU planned
     iii. DFU feasibility trial ongoing; results in 3Q2015
  7. Aesthetics and Repigmentation market offers a very lucrative value proposition
  8. Working towards strategic partnerships

- **Experienced management team working in close alignment with board**
- **Groundwork established for US institutional introduction in 2015**
- **Dedicated AU-based institutional investors eager to participant in upcoming fundraising events**

Use of Proceeds & Value Proposition

- **Avita Medical seeks to appoint US financial advisors to expand US investor base**
- **Use of proceeds will include:**
  - Prioritization of business development effort by recruiting proven team members
  - Appointment of global head of commercialization with track record in multiple geographies
  - Clinical trial funding; initiate new RCTs

- **Avita provides discerning investors an undervalued asset in the regenerative medicine space**
  - Successful clinical efficacy across multiple indications reproduced and corroborated by multiple investigators WW
  - Product platform that is already on the market WW, ex-US
  - Ongoing US clinical registration clinical trial (CTP001-6) provides a path to US market entry
  - Extremely large secondary indications in chronic wounds and aesthetic repigmentation
  - Ongoing randomized trial in VLU and feasibility trial in DFU provide near team catalyst
  - Commercial partnerships across all three indications catalysts and valuations inflexions
  - Excellent M&A target

For more information

www.avitamedical.com

Appendix – Finance / IP

Investment Team: Shareholders

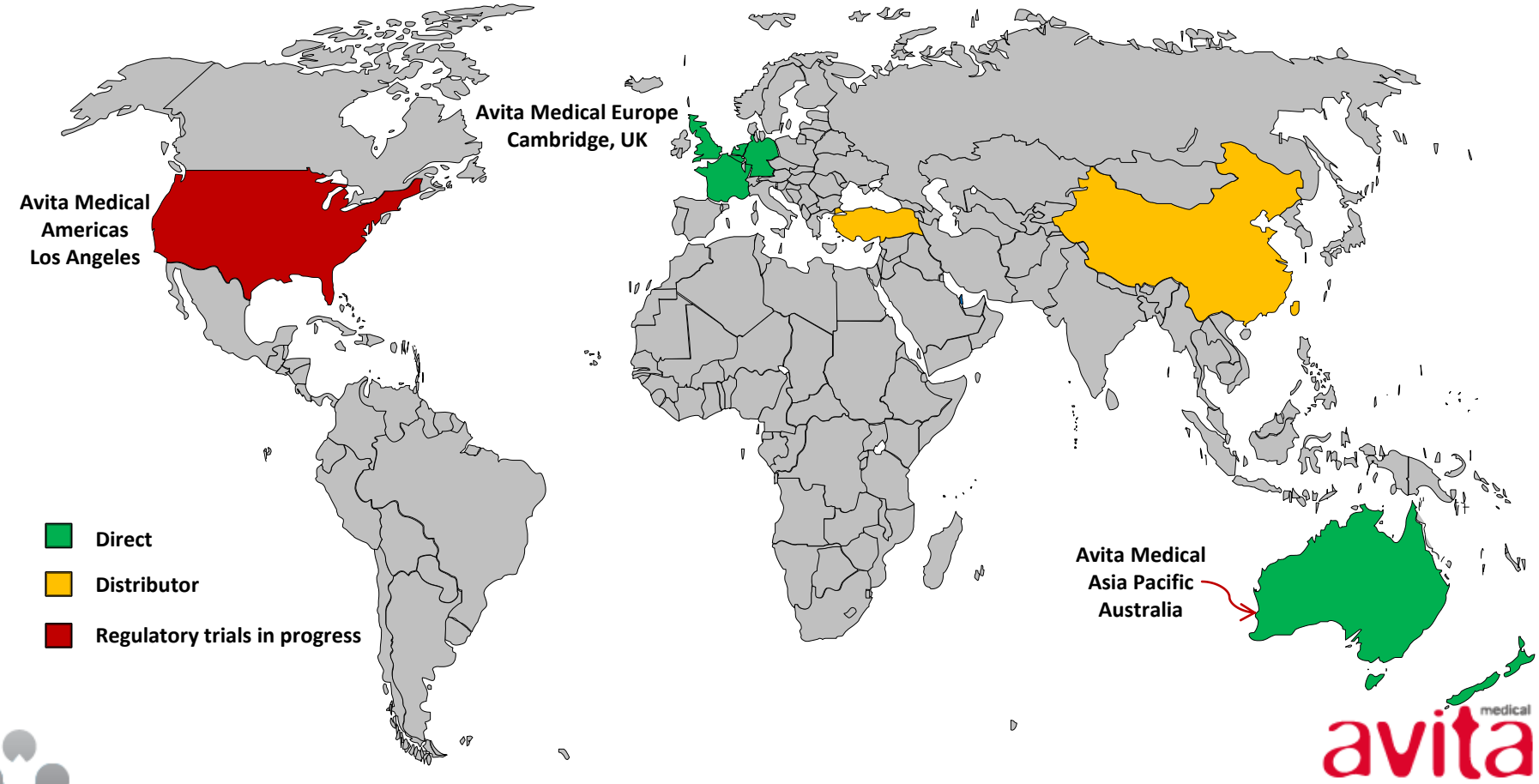
Shareholders

Rank	Holder	% CSO
1	Australian Ethical Investment Ltd	13.45%
2	National Nominees Limited	11.82%
3	One Funds Management Ltd	7.69 %
4	Citicorp Nominees Pty Ltd	6.32 %
5	Fats Pty Ltd / Ian Macpherson	3.08%
6	J P Morgan Nominees Australia Ltd	2.04 %
7	Moore Family Super Fund A/C	1.60 %
8	Scott Dibben Pty Ltd	1.40 %
9	Talico Overseas Ltd	1.23 %
10	Merrill Lynch (Aus) Nominees Pty Ltd	1.01 %

Financial Recap	
Ticker	ASX: AVH OTCQX: AVMXY
Share Price Jan 5 2015	A$0.08
Market Cap:	A$25.7MM
Cash Position: QE Sep 30 2014	A$2.3MM + A$1.4MM R&D credit
Cash Burn:	A$1.6MM/quarter
Annual Revenue: FY13-14	A$2.7MM
Debt:	$0MM

Sales generate growing revenue stream

Sales up 21% year over year (FY14 Vs FY13)



Avita: Peer Comparison

An undervalued public company in the regenerative medicine space

Company	Sector	Revenue FY2013	Net Profit FY2013	Market cap*	Exchange	Ticker
Avita Medical	**Regenerative**	**A$2.81M**	**-A$8.09M**	**A$35.8M**	**ASX**	**AVH**
Clinuvel	Regenerative	A$2.49M	-A$6.80M	A$67.8M	ASX	CUV
Tissue Therapies	Regenerative	A$95.00K	-A$5.74M	A$77.6M	ASX	TIS
Cytori Therapeutics	Regenerative	US$16.06M[1]	-US$19.96M[1]	US$186.8M	NasdaqGM	CYTX
Neostem	Regenerative	US$13.34M[1]	-US$42.31M[1]	US$233.4M	NasdaqCM	NBS
Mesoblast	Regenerative	A$34.71M	-A$61.66M	A$1.42B	ASX	MSB

Source S&P Capital IQ

*Market cap as at 5 June 2014

[1] Last 12 months as at 30 September 2013

Intellectual Property

- **Avita Medical's regenerative technology platform—ReCell, ReGenerCell and ReNovaCell are protected by a family of patents including:**
  - Unique composition of final product patents
  - Method of Production patents
  - Device patents
  - Automation patents for method and apparatus to generate epithelial suspension

- ✓ WW patents expire in 2022-2023—continuation-in-parts being filed to extend patent life
- ✓ US patents in review—will expire 2031 or later

Appendix – Acute Injury (Burns)

Decade of Clinical Experience With ReCell In Burns

Avita Sponsored Trials

Indication(s)	Study/N	Title & Results
Acute wounds & Plastics/Aesthetics (scar revision)	**PSR-01* N= 20** **(7 burns; 13post trauma scarring)**	A pilot study to evaluate the efficacy and safety of ReCell® Autologous Epidermal Cell Harvesting Kit in Epidermal Reconstruction **RESULTS:** • **ReCell found to be safe and well tolerated** • **All treatment areas healed after 1 week**
Acute wounds & Plastics/Aesthetics (scar revision)	**PSR-02* N=61** **(18 acute trauma; 43 skin defects scars/dyspigmentation**	A prospective study to evaluate the efficacy and safety of ReCell® Autologous Epidermal Cell Harvesting Kit in Epidermal Reconstruction **RESULTS:** • **ReCell safe and well tolerated without any systemic toxicity or vital signs changes** • **ReCell can be successfully used in combination with meshed skin grafts for full thickness burns** • **At Week 1, 46% of (ITT) cases had at least 80% re-epithelialization , 11% were healed (average re-epithelialization: 74%)** • **At Week 6, 88.5% of (ITT) cases were healed (average re-epithelialization: 99.7%)**
Acute wounds-cohort 1 (For US IDE Approval) RCT	**CTP001-5 N=101** (trial modified; in review)	A Comparative Study of the ReCell® Device and Autologous Split-thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries
Acute wounds-cohort 2 (For US IDE Approval) RCT	**CTP001-6 N=30** Initiate 1Q15	Demonstration of the Safety and Effectiveness of ReCell® combined with Meshed Skin Graft for Reduction of Donor Area in the Treatment of Acute Burn Injuries
Chronic wounds (VLU; pilot trial)	**CTP003** N=65** Ongoing in EU	A Pilot Randomized Controlled Trial of the Use of ReCell® Autologous Cell Harvesting Device for Venous Leg Ulcers

* Open label, non randomized trial

Clinical Experience With ReCell In Acute Injury (Burns)

Investigator Led Trials And Case Studies

Indication(s)	Study/N	Title & Results
Acute wounds	Gravante et al. 2007.*Burns* 33: 966. **N= 82** (42 ReCell; 40 classic mesh grafts)	A randomized trial comparing ReCell® system of epidermal cells delivery versus classic skin grafts for the treatment of deep partial thickness burns **RESULTS:** • **Donor area harvested- statistically significant in favor of ReCell** • **No tissue culture with ReCell saves time** • **Healing time comparable for ReCell and classic grafts** • **Comparable final appearance for ReCell and classic grafts** • **Comparable results with less donor area harvested and speed of therapy make ReCell a superior choice to classic grafts in large burns**
Acute Wounds	O'Neill et al. 2012. *Burns* 38:713.	Complex chemical burns following a mass casualty chemical plant incident: How optimal planning and organization can make a difference
Acute Wounds	Gilleard et al. Individual Case Study	ReCell in wound closure after skin cancer resection
Acute Wounds	Dunne et al. 2014. *Burns* 40: 772.	Letter To The Editor: Early pediatric scald surgery– A cost effective dermal preserving surgical protocol for all childhood scalds.

Clinical Data Supporting EU/RoW ReCell Approvals

- **The following clinical data were used in support of EU/RoW approvals:**
  - ★ **EU (CE Mark)- Mar 2005**
  - ★ **Canada* (Health Canada)- Jun 2006**
  - ★ **Australia (TGA)- May 2006**
  - ★ **China (sFDA)- Jul 2009**

  - Background evidence for cultured skin cell treatment
    - Literature review of cultural epithelial autografts (CEA) in burns
    - 11-year review of CEA (sheets and suspension) in Western Australia
    - Comparative treatment of donor sites with cultured cell suspension- Transepidermal Water Loss Study
    - Cultured glabrous cell suspension “take” on forearm

  - Clinical evidence for non cultured skin cell suspension (ReCell):
    - Literature review
    - PS-01 trial report
    - PS-02 trial report**
    - Melanocyte transfer study (Single center, clinical report of repigmentation of hypopigmented areas)
    - Multiple case reports: scar revision at dyspigmented sites (3); pediatric burn reports (2), hypopigmentation post C02 resurfacing for wrinkle reduction (1)
    - Safety database for ReCell in 197 patients treated under Australian Special Access Scheme

* ReCell is approved but not being marketed in Canada currently

** PSR-02 was the confirmatory basis of approval

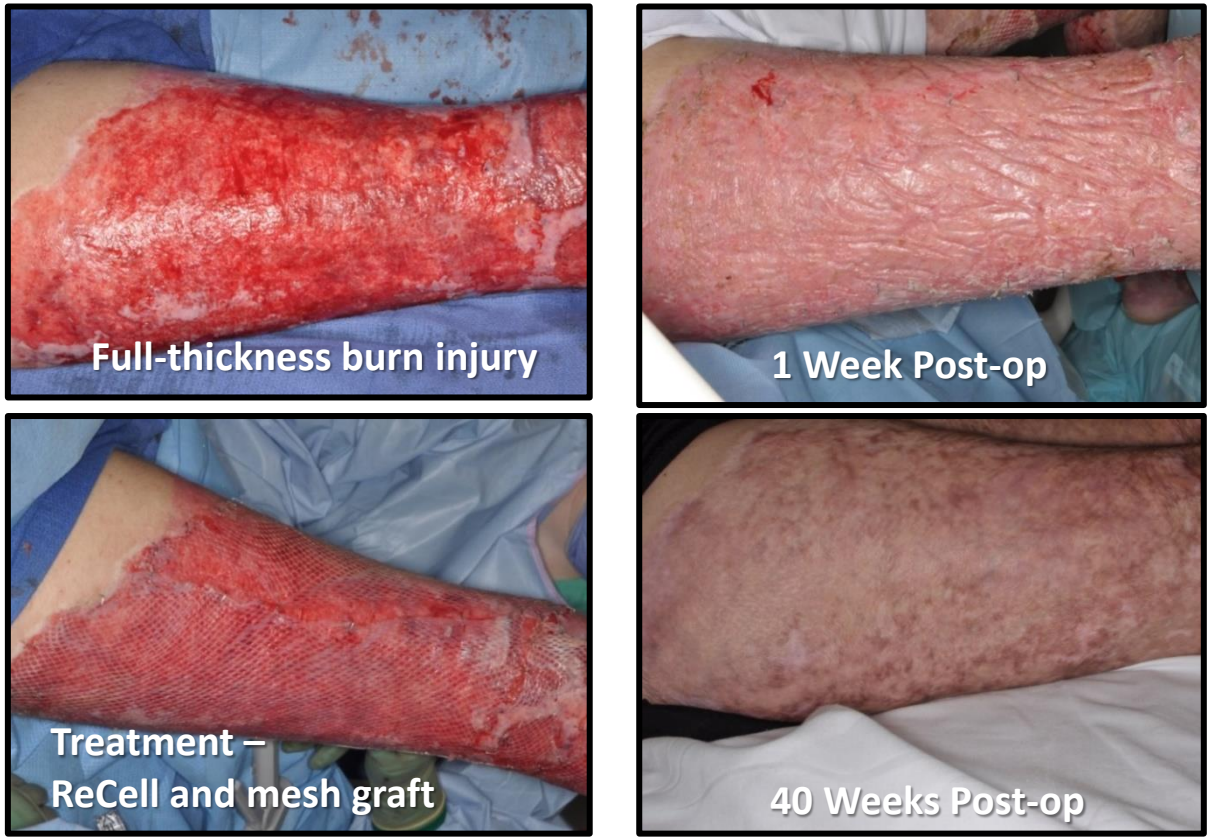
Advantages of ReCell in the Burn Care Setting

- **Ability to treat large burns with minimal donor site requirement—the unmet need in burn care**
  - 1cm^2 of healthy skin can generate 1ml of skin suspension to cover up to 80cm^2 of trauma surface

- **Rapid healing of donor site**
- **Avoids the need to isolate pure sub populations of skin cell types**
- **Avoids time consuming skin cell culturing**
- **Performed as a short 30-min procedure in the operating room**
- **Can be used with or without mesh grafting**
- **ReCell used along with mesh grafts can result in improved expansion ratio and reduced scarring than mesh graft alone**

ReCell Therapy in Combo with Mesh Graft: Evolving Standard of Care for Full Thickness Burn Injury

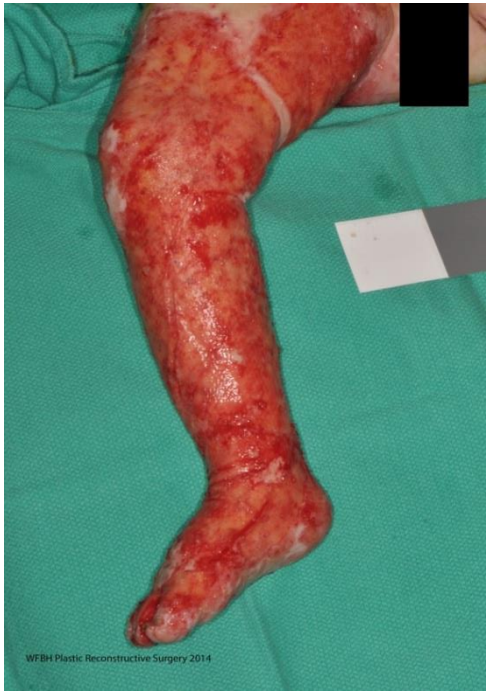
- Treatment of large surface/deep burns with limited donor site usage—unmet need in burn care
- ReCell (combo with mesh graft) designed for clinical efficacy with minimal donor site requirement
- Basis of NICE recommendation for ReCell research; design of the US pivotal trial



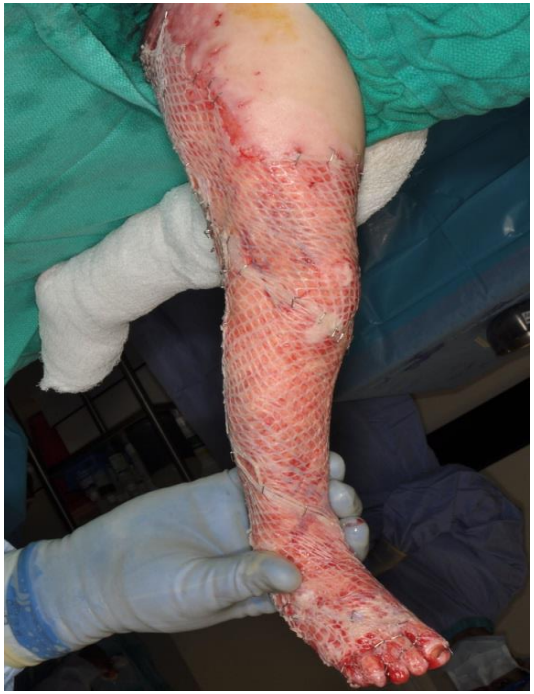
Key Value of ReCell: In the Treatment of Large Burns in Combination with Mesh Graft

(marked reduction in donor site requirement)

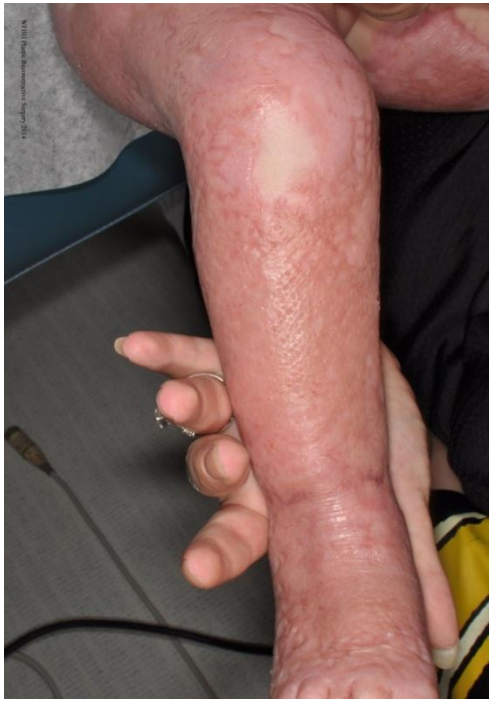
Case Study: 16-month old baby with 30% TBSA full thickness
Treated with ReCell and 3:1 mesh graft



Pre-treatment
Excised 3rd degree burn



Treatment
ReCell + Mesh Graft



Week 14 post treatment:

US IDE Approval Experience (CTP001-5)

Aim: Evaluation of the efficacy of ReCell autologous skin harvesting device versus autologous split thickness mesh graft for acute burn injuries

CTP001-5

- Sample Size: 90
- Final enrolled (N): 101
- Age: 18-65
- Second degree burns with confluent dermis
- Treatment area: 100-320cm^2/area
- % Burn: 1-20% TBSA#
- Centers: 12-15

Qualifying burn area bisected to randomize 1:1 for each patient

- **ReCell Autologous Suspension**
- **Mesh skin graft @ 2:1 expansion* ratio**

Endpoints & Assumptions:

1. **Incidence of 95% re-epithelialization at recipient site at 4 weeks**: Non-inferiority of ReCell Vs. mesh graft
2. **Incidence of complete closure of donor site at 1 week**: Superiority of ReCell Vs. mesh graft

TRIAL STATUS: CTP001-5 was modified in 2014 to resolve recruitment issues
Results being reviewed. Data expected 2Q15

TBSA= total body surface area; * expansion ratio= ratio of the size of the treatment area to the size of the donor area; α= standard of care

US IDE Approval Experience: Lessons Learnt From CTP001-5

The CTP001-5 shed light on the following problems-which would have eventually led to a restrictive and commercially unviable label for ReCell:

1. Inclusion/exclusion criteria created a very small niche of burn patients not representative of clinical practice at a burns center
   - Commercially unviable population of partial thickness injury with a confluent dermis

2. During the years of this study the SoC had shifted away from grafting of partial thickness burns
   - CTP001-5 control arm rendered moot

3. The successful US (compassionate use) and ex-US experience with ReCell has been in diverse kinds of mixed-depth and full- thickness injuries, with or without confluent dermis in combination with mesh graft
   - US trial (ReCell Vs. mesh graft) was not capitalizing on the ex-US experience with ReCell

4. Heterogeneity of follow-up care led to cases with “reopening” of wounds that had already re-epithelialized successfully, resulting in protocol violations
   - These violators would reduce the power of the study in an ITT analysis

5. Trial endpoints adjudication was based on treatment and donor site photographs reviewed by an independent reviewer
   - Absence of simple, direct endpoints created subjectivity, error-prone assessments

US IDE Approval Experience (CTP001-6)

Aim: Evaluation of the efficacy of ReCell in combination with meshed skin graft for the treatment of all acute burn injuries

(Red font indicates protocol changes in CTP001-6 compared to CTP001-5

CTP001-6

- Sample Size: 25
- Target enrollment (N): 30
- **Age: ≥5yrs**
- **All burns requiring skin grafts (2nd & 3rd degree)**
- **Treatment area: 300+ cm^2 /area**
- **% Burn: 5-50% TBSA**
- Centers: 4-6

Qualifying burn area bisected to randomize 1:1 for each patient

ReCell autologous suspension in combination with protocol defined wider mesh graft

Conventional skin graft

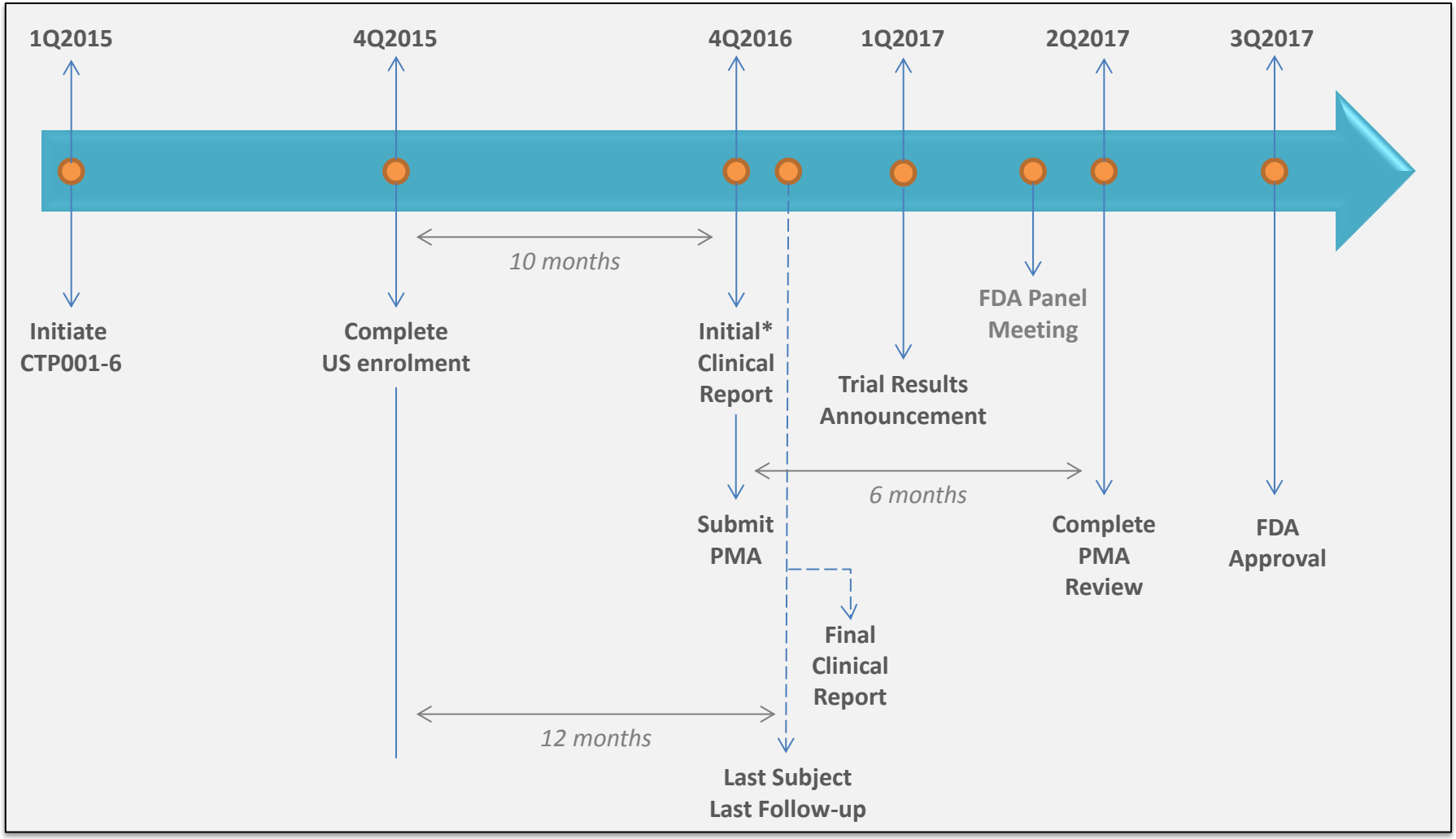
Endpoints & Assumptions:

1. **Incidence of complete closure rate of recipient site at 8 weeks***: Non-inferiority of ReCell/Mesh combo versus graft alone
2. **Expansion ratio at time of treatment**: Superiority** of ReCell/Mesh combo versus graft alone

- **Less stringent inclusion/exclusion criteria will allow faster enrolment**
- **More objective primary endpoints will reduce variability and allow smaller sample size**
- **"Real world" use of ReCell/mesh graft combo will allow broad label and extensive use**

* Additional procedures aiding wound closure allowed within initial 8 weeks; ** ReCell expansion ratio: control expansion >1

US ReCell Burns Approval Timeline



*Complete effectiveness data
& interim (9-month) safety data

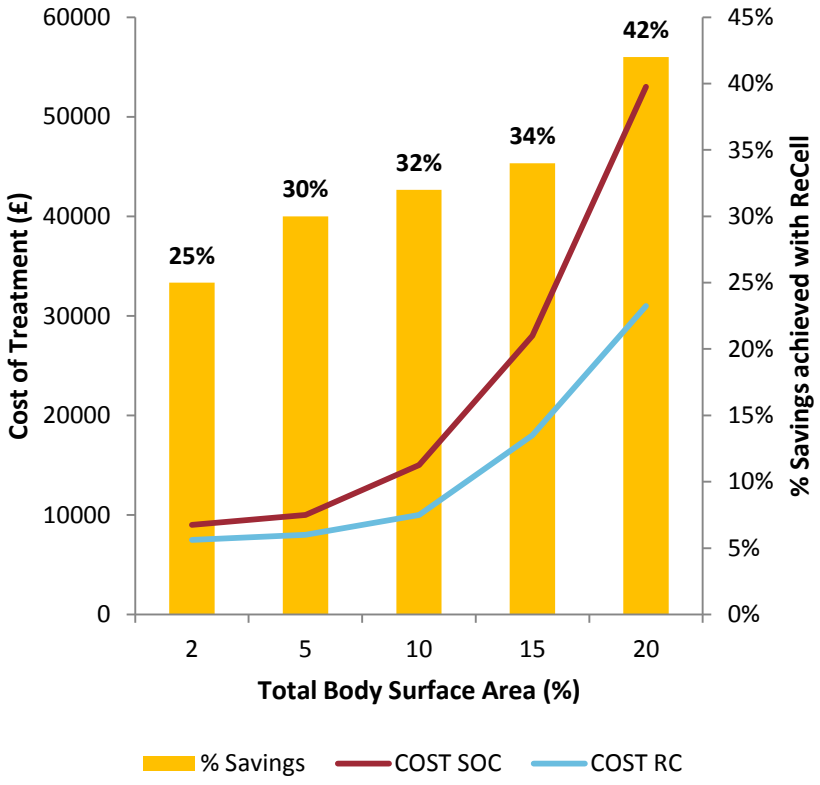
EU/RoW Reimbursement Strategy For ReCell

Clinical & Pharmaco Economic Data To Prove Superiority of ReCell Over SoC

- **Shortening acute surgery** duration with ReCell independently predicts the length of stay in the burn centre[1,2]
- Patients with ReCell surgery were likely to have a **shorter length of stay** compared to patients with split skin grafting (SSG) surgery alone[2]
- **Faster wound healing, reduced donor site morbidity and better functional** and aesthetic scar outcomes make ReCell a preferred choice[3]
- **Reduced analgesic and dressing costs** with ReCell saved 29% compared to conventional delayed surgery for non-healing wounds[3]

[1] Lim et al. 2013. *Is the length of time in acute burn surgery associated with poorer outcomes?*
[2] Park et al. 2013. *Does the type of skin replacement surgery influence the rate of infection in acute burn injured patients?*
[3] J.A. Dunne. 2013. *Early paediatric scald surgery—A cost effective dermal preserving surgical protocol for all childhood scalds.*

Greater The Burn Surface- More The Cost Effectiveness of ReCell Therapy



N= 22; Pinderfields Hospital Burns Unit internal data; 2011

Key Developments In EU/RoW Reimbursement Strategy For ReCell

United Kingdom

- **NICE commissioning research to verify the value proposition of ReCell in combination with mesh graft; additional data from CTP001-6 will also be submitted for updated guidance**

Germany

- **Supporting application submitted by eight hospitals, multiple authorities involved including:**
  - InEK: Institute for the Hospital Remuneration System
  - DIMDI: German Institute of Medical Documentation and Information
  - G-DRG: Diagnosis Related Group; ICD-10-GM 'German Modification'

Turkey

- **ReCell has been classified with a code and placed on the 'positive list' for temporary reimbursement until permanent status can be achieved.**

Australia, France and Italy

- **Process is underway**
- **Sales of ReCell have been up 58% YoY in EU (ex-UK) and 25% in AU despite absence of formal reimbursement structure**

avita medical

NICE: National Institute for Health And Care Excellence (UK)

Appendix – Chronic Wounds (VLU, DFU)

The Biology of Chronic Wounds

- **Any wound open > 4-6 weeks**
- **Underlying pathophysiological cause including:**
  - hypoxia (venous leg ulcers; VLU)
  - hyperglycemia (diabetic foot ulcers; DFU)
- **Impaired keratinocyte proliferation**
- **Abnormal morphology and diminished proliferative capacity of fibroblasts**
- **Management of chronic wound hence requires debridement to remove barriers that impair wound healing to restore an acute environment**
  - The conversion of a chronic wound to an acute stage can accelerate healing

Loots et al., 1999. *Arch Dermatol Res.* 291:93-99
Falabella et al, 2006. *Dermatol Ther* 19(6): 317-325

Market Opportunity in Chronic Wounds

Chronic Wounds (Lower Limb Ulcers)	Prevalence				Associated Revenue Potential*
	US *pop. 316M (11.4% diabetes[1])*	**UK, FR, DE, IT** *pop. 271M (8% diabetes[1])*	**Aus** *pop. 23M (5.1% diabetes[1])*	**China** *pop. 1.4B (9.3% diabetes[1])*	
VLU: 1% of pop.[2]	VLU: 3.2M	VLU: 2.7M	VLU: 0.2M	VLU: 13.6M	$66B
DFU: 15-25% of diabetics[3,4]	DFU: 9.0M	DFU: 5.5M	DFU: 0.3M	DFU: 31.6M	
TOTAL					**~$66B**

*assume one device @ $1,000 per patient ASP

[1] International Diabetes Federation (IDF) Diabetes Atlas, Sixth Edition (2014)
[2] **[VLU prevalence 1% of population]:** Humphreys, M. L., A. H. R. Stewart, M. S. Gohel, M. Taylor, M. R. Whyman, and K. R. Poskitt. "Management of mixed arterial and venous leg ulcers."*British Journal of Surgery* 94, no. 9 (2007): 1104-1107.
[3] **[Lifetime incidence= 15-25% of diabetics]:** Singh, Nalini, David G. Armstrong, and Benjamin A. Lipsky. "Preventing foot ulcers in patients with diabetes." *JAMA* 293, no. 2 (2005): 217-228.
[4] International Diabetes Federation Diabetes Atlas, Sixth Edition (2014)

Venous Leg Ulcers (VLU)

- Hypoxia related venous insufficiency can interfere in cutaneous and subcutaneous tissue maintenance and healing causing lower limb ulcers called VLU [1, 2]
- VLU occurs in up to 1% of the general population of a western country & 3% of the geriatric population [3, 4]
- Despite interventions to fix the venous insufficiency the affected tissue can remain ulcerous for an extended time ~ **40% ulcers remain unhealed** [1, 2]
- VLU results in severe pain, poor QoL, reduced mobility and sleep disorders
- SOC for VLU is compression therapy
- Novel therapies- laser and infrared therapy, vacuum assisted closure, hyperbaric O_2 therapy show limited promise[5-6]
- In 2010-11 skin grafting with artificial bilayer showed promise for VLU
  - **This prompted two (Giraldi, De Angelis) investigator led exploratory trials of ReCell in VLU [7, 8] using immediately available suspension as an alternative to CEA***

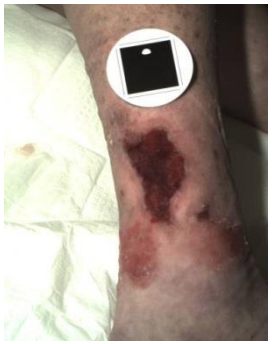
*** CEA= cultured epithelial cells**

1. Krishnamoorthy et al., 2003. *Phlebology* 18(1): 12
2. Margolis et al. 2009. *Wound Repair & Regeneration* 17(3):318
3. Nelzen, 2008. *Phlebolymphology* 15(4):143.
4. Nelson & Jones. 2008. Clinical Evidence, pii.1902.
5. O'Meara et al. 2009. Cochrane Database of Reviews
6. Scottish Intercollegiate Guidelines Network. 2010
7. Giraldi et al. 2012. Acta Vulnol. 10(3): 153.
8. De Angelis et al. 2013. Intl. Wound J. ISSN 1742.

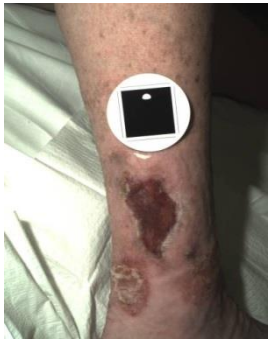
ReGenerCell: Complete Wound Closure Can Be the New Benchmark in Chronic Ulcer Treatments

- **Closure of long term open ulcers— is the unmet need in chronic wound care**
  - Such chronic ulcers are secondary to hypoxia (VLU) or hyperglycemia (DFU)
- **Current therapies only provide supportive care, focusing on wound management <u>not wound closure</u>**
- **ReGenerCell provides a novel autologous wound closure treatment for such patients**
  - ReGenerCell can reduce rate of limb amputation, pain, and restore quality of life

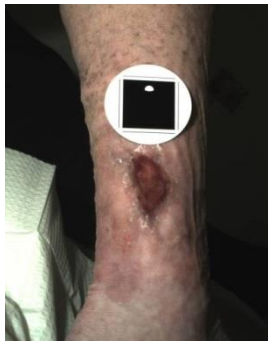
Case Study: 67 yr old female with PAD*, type II DM*, VLU on right leg open 46 wks



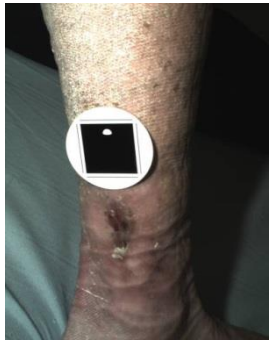
Baseline
VLU area = 10cm^2
ReGenerCell Treatment



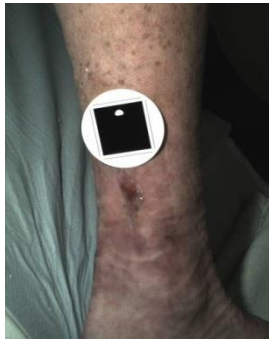
Week 1



Week 6
VLU area = 3cm^2
ReGenerCell Retreatment



Week 11
VLU area < 1cm^2

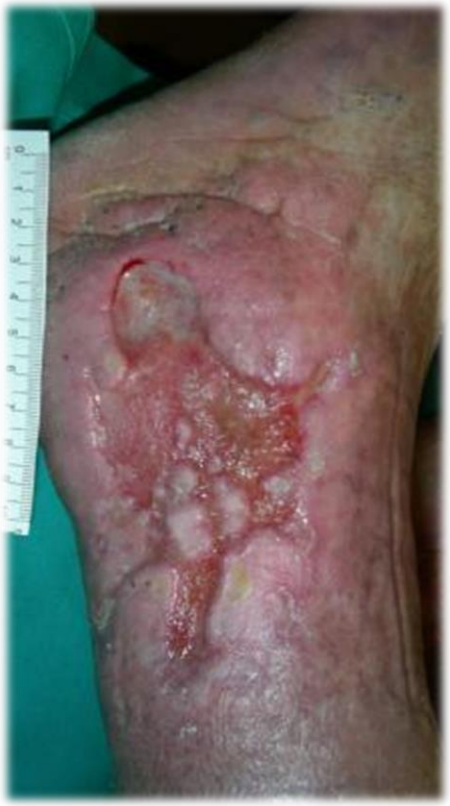


Week 13
100% closure

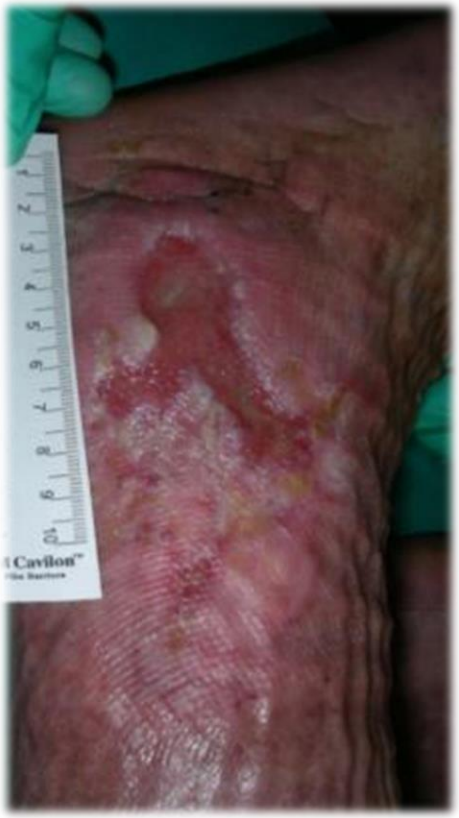
* PAD= peripheral arterial disease; DM= diabetes mellitus

ReGenerCell Therapy Can Achieve the Unmet Need of Complete Wound Closure for Chronic Ulcers

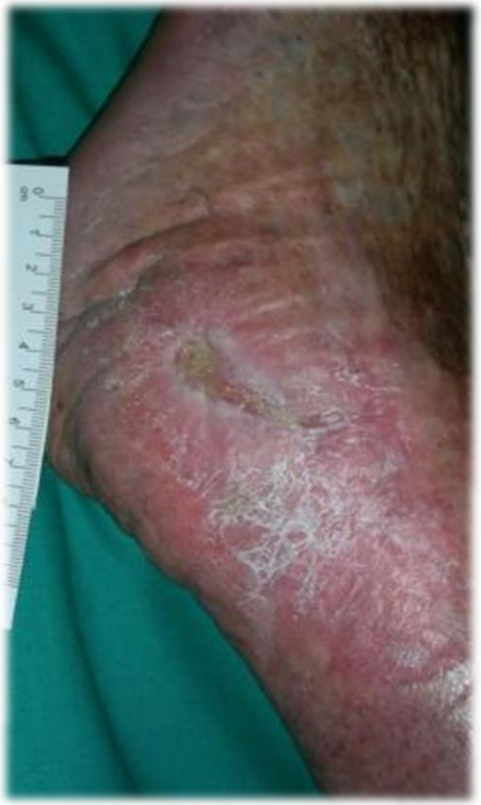
Case Study: 84 yr old male with controlled high BP, colon cancer in remission, chronic venous insufficiency. Left ankle VLU open 7 yrs treated with ReGenerCell.



Baseline
VLU area = **55cm²**
ReGenerCell Treatment



Week 7
VLU area = **8cm²**
% Re-epithelialization vs baseline= 85%



Week 20 (5 mo)
VLU area = **2cm²**
% Re-epithelialization vs baseline= 96%

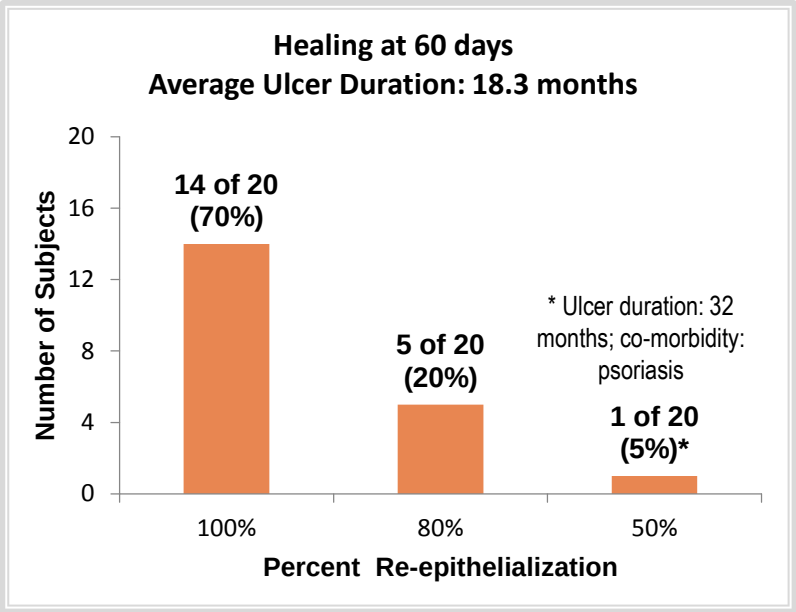
Clinical Experience with ReGenerCell in Chronic Wounds

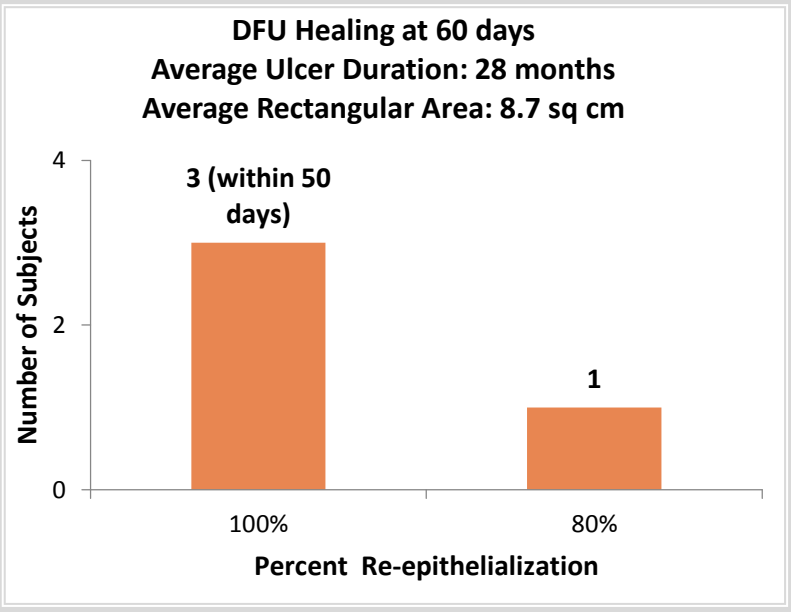
Investigator Led Trials And Case Studies

Indication(s)	Study	Research Title
Chronic Wounds VLU	Giraldi et al. 2012. *Acta Vulnologica* .10 (3):153.	Preliminary results with the use of a non-cultured autologous cell suspension to repair non-healing vascular leg ulcers
Chronic Wounds VLU & DFU	De Angelis et al. 2013. *Intl. Wound J.* ISSN:1742.	The use of a non cultured autologous cell suspension to repair chronic ulcers
Chronic Wounds (wound healing after diabetes related amputation)	Chant et al. 2013. *J. Wound Care.* 22(10);510.	Autologous skin cells: A new technique for skin regeneration in diabetic and vascular ulcers
Chronic Wounds VLU	Trapasso et al. 2013. Plast. Reconstr. Surg. Glob. Open. 1(2): 1.	Regenerative Surgery for the Definitive Repair of a Vasculitic Nonhealing Ulcer Using Platelet-derived Growth Factors and Noncultured Autologous Cell Suspension. A case study.

Exploratory Investigator Led Trials Paved the Way to Development for Chronic Wounds

- 70% of ulcers healed within 60 days of treatment
- Mean duration of ulcers= 18 mo; mean age of pts= 70 yrs

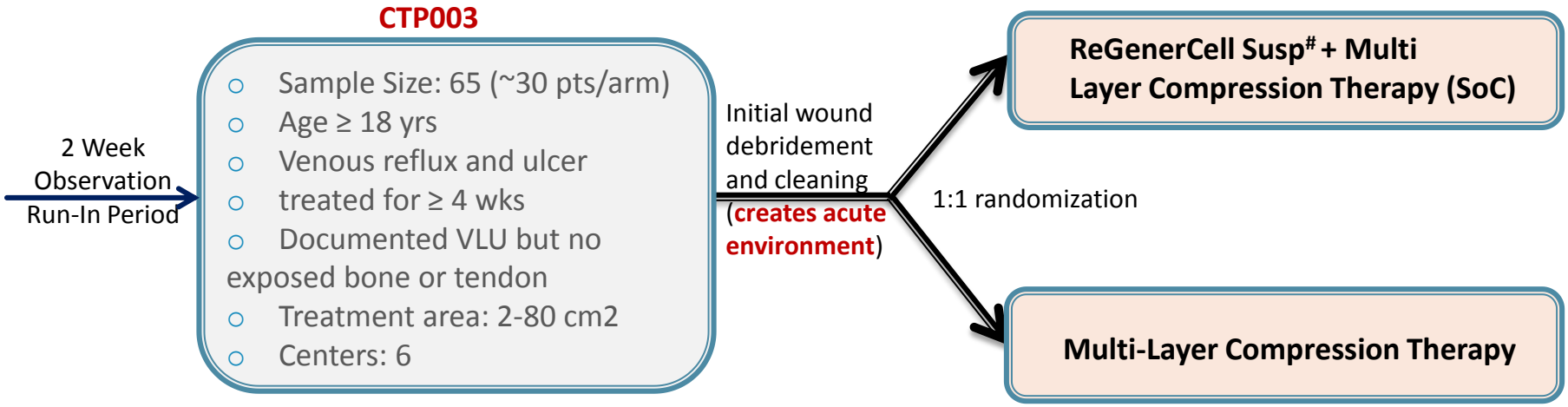




B De Angelis et al, 2013. The use of a non cultured autologous cell suspension to repair chronic ulcers, *International Wound Journal ISSN 1742-4801*

Pilot Trial for ReGenerCell in Venous Leg Ulcers (CTP003)

Aim: Evaluation of the efficacy of ReGenerCell in combination with standard compression device Versus standard of care for the closure of venous leg ulcers (VLU)



Endpoints:

1. **Incidence of ulcer closure* at 12 weeks post randomization**: Assumes superiority of ReGenerCell over SoC
2. Patient reported pain & quality of life
3. Treatment cost differential between ReGenerCell and control
4. Adverse event profile; safety of ReGenerCell in VLU

TRIAL STATUS: Trial initiated 3Q2013; final results 3Q15

ReCell patients are eligible for repeat ReCell therapy at study week 6-7 if the extent of wound epithelization is < 85% but > 15%

* Ulcer closure is defined as complete re-epithelialization without drainage

US Market Entry Timelines for VLU

Description	Target Date
Complete VLU pilot trial enrolment	1Q2015
VLU pilot trial results	**3Q2015**
Use pilot trial results in VLU for label expansion (EU, AU, China, Canada)	**4Q2015**
Begin planning the pivotal US VLU trial for IDE submission	2015
Pre-IDE meeting with FDA	YE2015
Submit IDE application to FDA/ application acceptance	2Q2016
Commence pivotal US VLU clinical trial	4Q2016
Report pivotal US VLU trial results	**Mid-2019**
FDA PMA submission for VLU	YE2019
FDA approval of ReCell/ReGenerCell in VLU	2Q2020
US Launch in VLU	**3Q2020**

Diabetic Foot Ulcers (DFU)

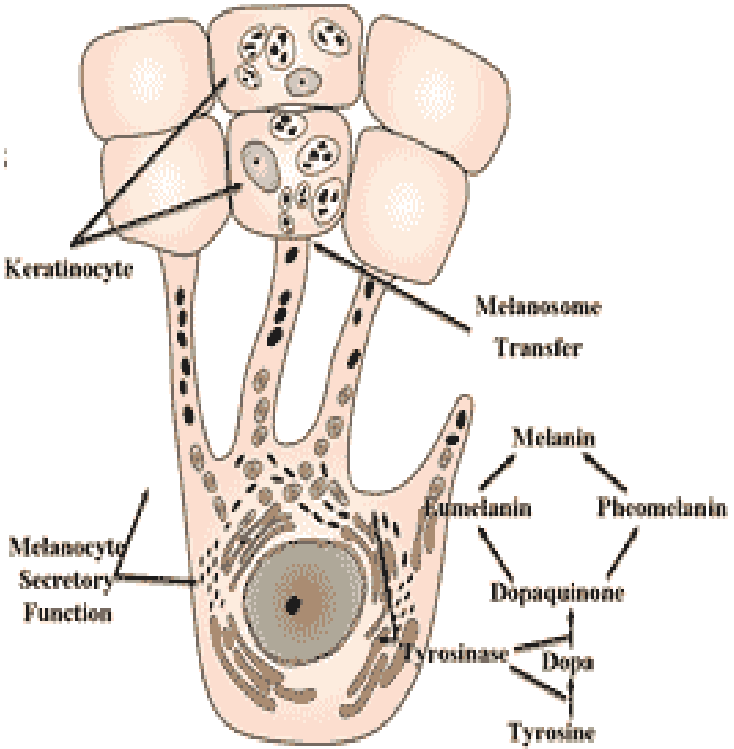
- DFU is a major complication of diabetes mellitus and affects 15-25% of all diabetics [1, 2, 3]
- DFU precedes 85% of diabetes related foot amputation[2, 3]
- There is no standard of care for the treatment of DFU and it represents one of the highest unmet medical needs
- In the absence of approved therapies, DFU is currently managed with extracellular matrix therapy, negative pressure therapy, hyperbaric O_2 therapy and moist wound therapy[3]
- Independent investigator initiated studies have demonstrated the efficacy of ReCell in wound healing in DFU patients
  - Chant et al[4] showed promise for use of ReCell in wound closure/healing for diabetics
  - De Angelis and coworkers[5] have demonstrated 80-100% re-epithelialization rates using ReCell in 4 patients with DFU
- **Avita sponsored feasibility study for ReGenerCell in DFU (UK); Results 3Q15**
- **Success on feasibility trial will trigger a randomized pilot trial of ReGenerCell in DFU in 2016 with a goal of a pivotal study in 2017 and FDA PMA submission by 2020**

1. Singh et al. 2005. *JAMA* 293, no. 2 (2005): 217.
2. International Diabetes Federation Diabetes Atlas, Sixth Edition (2014)
3. American Diabetes Association website
4. Chant et al. 2013 J. Wound Care: 22(10):510.
5. De Angelis et al. 2013. Intl. Wound J. ISSN 1742

Appendix – Aesthetics (pigmentation)

Skin Repigmentation: The Biology

- Restoration of pigment in hypo-pigmented skin is a complex biological process
- Skin pigmentation is proportional to the number and activity of skin melanocytes
- Melanocytes are specialized skin cells containing sub cellular structures called melanosome expressing the pigment melanin—responsible for skin color
- Each melanocyte interacts through dendrites with 30-40 keratinocytes allowing transfer of mature melanosomes to the cytoplasm of keratinocytes
- **Melanocytes are extremely sensitive to stress leading to their death or senescence**
- **Direct melanocyte injury or damaged keratinocytes causing secondary melanocyte injury/death result in de-pigmentation**



Videira et al., 2013. *Ann. Bras. Dermatol.* 88(1): 76.

Skin Repigmentation Therapy: The Unmet Need

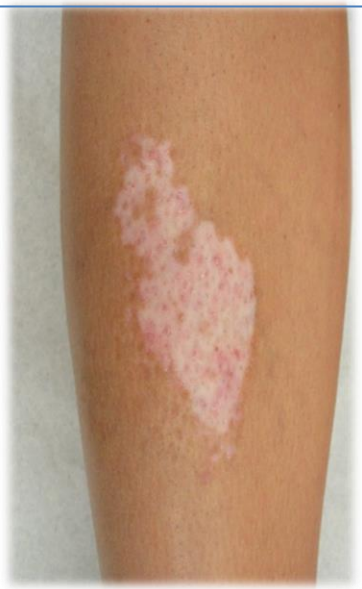
- Homogenous repigmentation of hypo-pigmented skin is unmet medical need
- Causes of hypo-pigmentation may include:
  - Scarring after acute or chronic wounds
  - Aesthetic procedures including skin resurfacing
  - Genetic/autoimmune de-pigmentation defects—vitiligo
- Nonsurgical options "lotions and potions" and light therapy sometimes efficacious
- Melanocyte transfer is the only surgical available treatment for re-pigmentation; it is time consuming and expensive
- ReCell/ReNovaCell – novel autologous cell suspension offers a simplified "off-the-shelf" solution for homogenous repigmentation of depigmented skin
- **Working Theory:** autologous cell suspension contain melanocytes to replace absent or dead/damaged melanocytes at the transplantation site. By responding to the local milieu of transplant and the growth factors secreted by co-transplanted keratinocytes and fibroblasts, the new melanocytes can generate a homogenous pigment at their new destination

avita medical

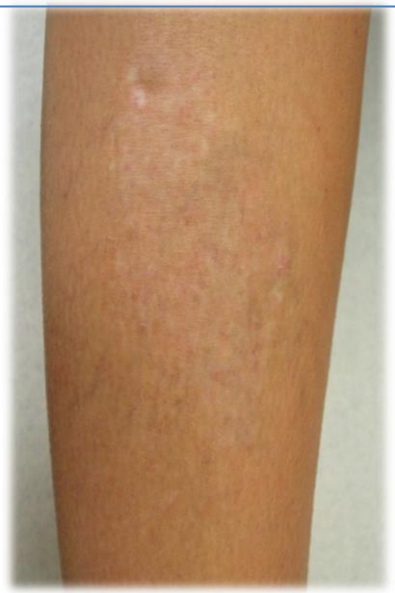
ReNovaCell In Aesthetics & Repigmentation

- In the early 2000's Avita Sponsored PSR-01 and PSR-02 studies first demonstrated proof of ReCell (now, ReNovaCell) efficacy in scars revision and repigmentation;
- Two recently completed randomized trials with objective measures of repigmentation demonstrate statistically significant benefit with ReNovaCell vs controls
- Together they provide a sufficient proof of efficacy and launch of ReNovaCell in ex-US territories
  - **EU CE-Mark: 1Q2015** **AUS (TGA): 3Q2015** **China (sFDA): YE2015**
- US clinical strategy for ReNovaCell in Aesthetics under review; US commercial strategy based on partnering with pharma

Case Study: ReNovaCell for Vitiligo



Pre-treatment



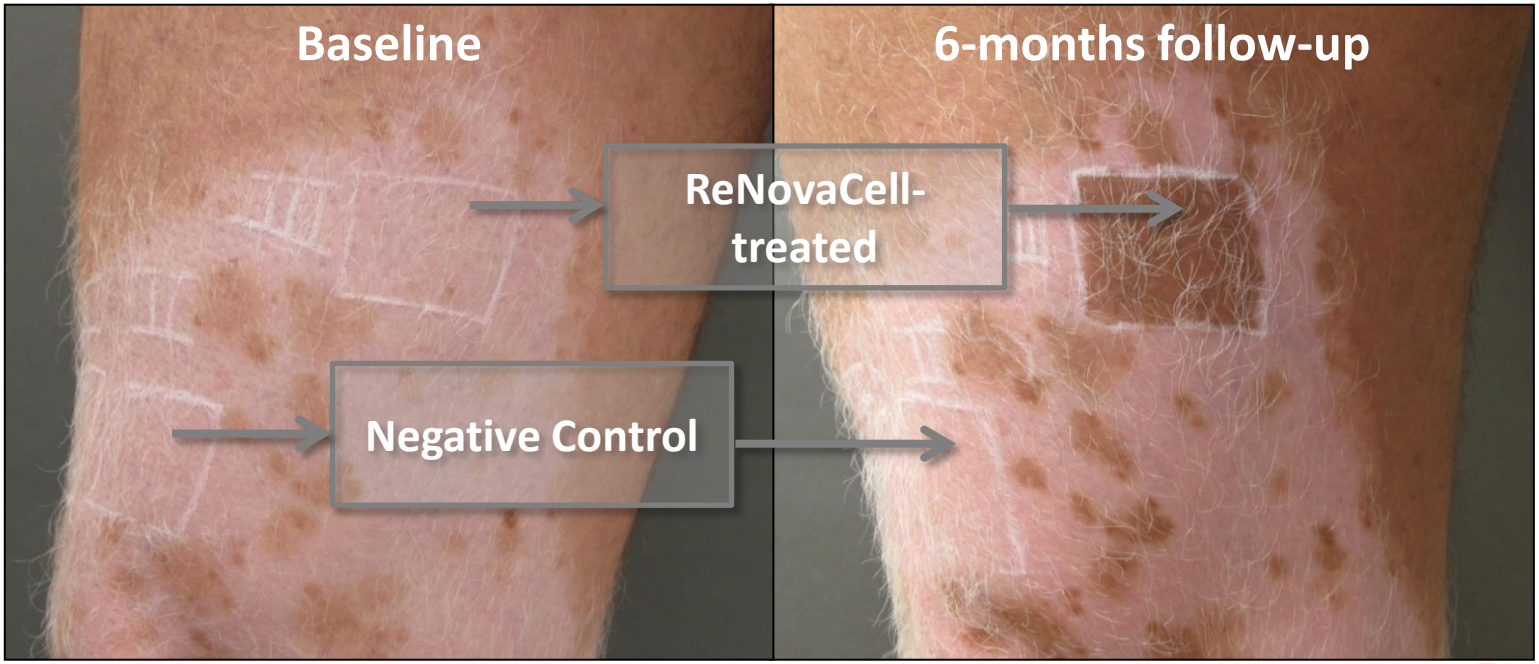
18 wks post treatment

Courtesy of L Komen & A Wolkerstorfer; Netherlands Institute for Pigmentation Disorders

ReNovaCell: Simple Solution for Skin Repigmentation

- Re-pigmentation of hypo-pigmented skin due to old age, injury, skin treatments, vitiligo– is the unmet medical need in aesthetic dermatology
- Nonsurgical options “lotions & potions” and light therapy is sometimes efficacious
- Melanocyte transfer is the sole surgical choice for repigmentation but expensive, time consuming
- ReNovaCell is the only simplified, cost-effective solution for skin re-pigmentation with rapid results (1-6 months)

Case Study: patient with segmental vitiligo (duration > 5yrs)



Clinical Experience With ReNovaCell In Repigmentation—Aesthetics And Vitiligo

(Dossier for launch of ReNovaCell in ex-US territories)

Indication	Author/Publication	Research Title
Plastics/Aesthetics Scar revision Repigmentation	Busch et al.2014. *J Pigmentary Dis*. 1:122	Combination of Medical Needling and ReCell® for Repigmentation of Hypopigmented Burn Scars
Plastics/Aesthetics Repigmentation	Mulekar et al. 2008. *Br. J. of Dermatol*. 158(1):45	Treatment of vitiligo lesions by ReCell® vs. conventional melanocyte–keratinocyte transplantation: a pilot study
Repigmentation/ Vitiligo (RCT)*	Wolkerstorfer et al: In press	Autologous cell suspension transplantation using a cell harvesting device in segmental vitiligo and piebaldism patients: a randomized controlled pilot study
Plastics/Aesthetics	Dunne et al. 2013. *Br.J, Oral Maxillofacial Surg*. 51: 282	Management of rhinophyma with Verasjet and ReCell
Repigmentation	Hivelin (Case Study)	Study of Recell in pigment mismatch on flap
Plastics/Aesthetics	O'Neill (Case study)	Nevus?
Vitiligo	Cervelli (Case Study)	Case Study in a patient with Vitiligo hands
Plastics/Aesthetics (RCT)*	Gramlich (Case Study)	ReCell in combination with Laser rejuvenation in skin smoothening

* RCT= randomized controlled trial

Appendix – Biology of Skin

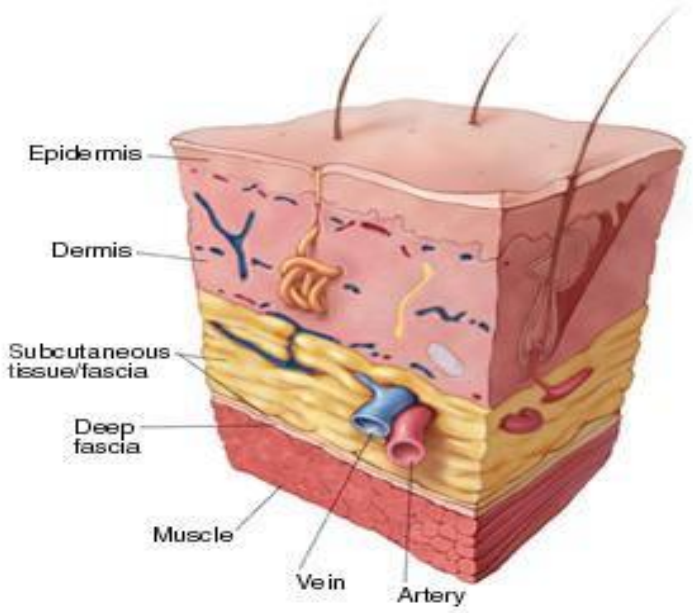
Wound Healing: Sequence of Events

- **Epithelialization is used as a defining parameter of wound healing success**
- **Healing of a wound requires a well orchestrated integration of the complex biological and molecular events of**
  - Keratinocytes initiate re-epithelialization process and epidermal maturation
  - Fibroblasts can re-initiate the proliferative phase by increasing number of fibroblasts in the ECM
  - Multiplying fibroblasts result in wound closure, dermal restoration
  - Keratinocytes and fibroblasts secrete heat shock proteins (hsp90), growth factors, cytokines
  - Hsp90 is required for wound site angiogenesis, cell migration and matrix remodelling
  - EGF/TGF/FGF promotes proliferation, VEGF induces angiogenesis, PDGF aids collagen formation, etc.
- **Partial thickness wounds (restricted to dermis) still have a reservoir of keratinocytes and a residual ECM**
  - They heal from the edges and from within the wound
- **Full thickness wounds lack keratinocytes, fibroblasts and ECM structure**
  - They can only heal from the edges and contraction is important for wound closure; ECM must be restored with skin grafts

Falanga et al, 2005.*Lancet*: 366:1736-1743

Skin Biology and Acute Wounds

- **Human skin is made up of three layers**
  - Epidermis
  - Dermis
  - Hypodermis/subcutaneous
- **Layers of the skin consist of four cell types**
  - Keratinocytes
  - Fibroblasts
  - Melanocytes
  - Langerhans cells



- **An acute wound is characterized by a cutaneous (skin) injury which heals readily and with no underlying pathophysiological barriers**
  - Cuts, abrasions, burns
- **Acute wounds face evolutionary pressure to repair quickly and with the least energy**
  - Therefore acute wounds heal with a scar and no regeneration

Falanga et al, 2005.*Lancet*: 366:1736-1743

The Biology of Chronic Wounds

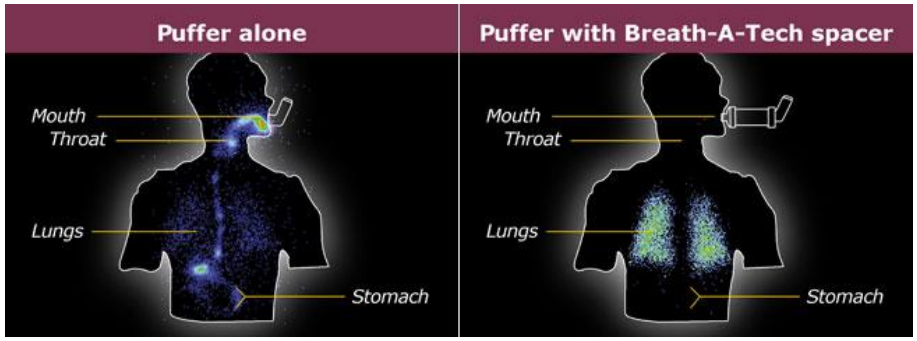
- **Any wound open > 4-6 weeks**
- **Age of ulcer predicts degree of impairment and lack of restorative milieu**
- **Underlying pathophysiological cause including:**
  - hypoxia (venous leg ulcers; VLU)
  - hyperglycemia (diabetic ulcers)
- **Impaired keratinocyte activity**
- **Abnormal morphology and diminished proliferative capacity of fibroblasts**
- **Management of chronic wound hence requires debridement to remove barriers that impair wound healing to restore an acute environment**
  - The conversion of a chronic wound to an acute stage can accelerate healing

Agren et al. , 1999. *J. Inv. Dermatol.* 112:463.
Loots et al., 1999. *Arch Dermatol Res.* 291:93-99
Falabella et al, 2006. *Dermatol Ther* 19(6): 317-325

Appendix – Legacy Business (Respiratory)

Breath-A-Tech Spacer For Asthma Inhalers

- The respiratory platform (Breath-A-Tech and Funhaler) are legacy products inherited from the VisioMed reverse merger
- Breath-A-Tech is a medical grade spacer used in inhalers for patients with asthma.
- Clinical work has demonstrated that the Breath-A-Tech spacer allows more targeted delivery of inhaled medications deep into the small airways of the lungs



- The Breath-A-Tech spacer is a market leader in Australia due to its compact size, cost-effectiveness and easy clean up; a pediatric version call Funhaler is also available
- Breath-A-Tech is sold through the wholesale channel where the wholesalers act as the *de facto* sales force for this product and sell it downstream to hospitals and pharmacies throughout Australia
- Breath-A-Tech is also the preferred in-patient choice in Australia because it can be detached and autoclaved and meet hospital hygiene standards

Corporate Update on Respiratory Product Line

- **Management explored divestiture options and has now resolved to reinvigorate the line with renewed focus and specific initiatives**
- **An increased investment in the line with the following initiatives is anticipated to stimulate additional revenue, as the respiratory line experienced a revenue drop of 8% from prior year**
  - Building an AUS East Coast based sales team
  - Increase cooperative advertising budget
  - Pricing programs
  - Product Innovation
  - New focus on Primary Care GP's
  - Partnerships with local Asthma Foundations
  - Increased presence amongst community groups