



**Andrew Quick**  
**Sr VP Clinical Development**  
**October 6, 2016**



# Disclaimer – Forward Looking Statements

---

This presentation may include forward-looking statements. You can identify these statements by the fact that they use words such as “anticipate”, “estimate”, “expect”, “project”, “intend”, “plan”, “believe”, “target”, “may”, “assume” or similar expressions.

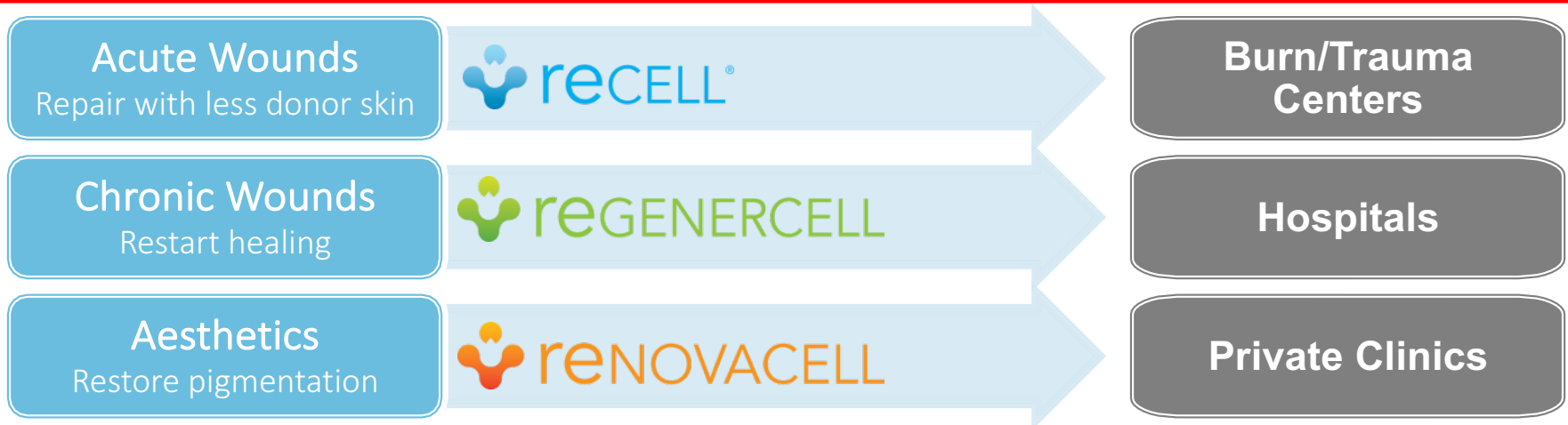
These forward looking statements speak only as at the date of this presentation and are based on management’s expectations and beliefs concerning future events. Forward-looking statements are necessarily subject to risks, uncertainties and other factors, many of which are outside the control of Avita Medical that could cause actual results to differ materially from such statements.

Avita Medical makes no undertaking to subsequently update or revise the forward-looking statements made in this release to reflect events or circumstances after the date of this release.

This presentation is intended to provide background information only and does not constitute or form part of an offer of securities or a solicitation or invitation to buy or apply for securities, nor may it or any part of it form the basis of, or be relied on in any connection with any contract or commitment whatsoever.



# Avita Medical – Company Background



- Platform autologous cell harvesting technology addressing unmet need in clinical indications encompassing a range of skin injuries and defects
- Publicly traded in Australia (ASX:AVH) and US ADRs (OTCQX:AVMXY)
- Products cleared for marketing in EU, Australia, China
- U.S. HHS BARDA contract (US\$61.9m) for support of PMA & Pre-EUA activity, US burn center familiarity and acceptance, and to establish a national strategic stockpile of ReCell® for mass casualty preparedness
- US FDA Pivotal Trial for ReCell in burns fully recruited and participants are being followed
- Operational build centered on the LA office, as the hub of Clinical, Quality, Regulatory, Supply Chain Financial, and US Sales & Marketing activities

**A Global Pioneer in Regenerative Cell Therapy**



**avita**<sup>medical</sup>  
transforming lives

# Skin Regeneration Platform

- Autologous Cell Harvesting Devices used to treat wounds and skin defects
  - Proprietary Enzyme formulation,
  - Processing unit including sterile enzyme soak-, buffer rinse- and filtering- chambers and a sterile tray for mechanical disaggregation of skin sample
  - Validated set of applicators designed to overlay wound area with suspension of healthy cells
- Allows rapid creation of Regenerative Epithelial Suspension™ (RES™)
  - Disaggregated (activated/“free-edge”), autologous skin cells (keratinocytes, fibroblasts, melanocytes)
  - Signaling factors (cytokines, chaperones like hsp90, growth factors)
  - Catalyze regenerative healing upon application to wound

## Vital Statistics

1. 1 hour to learn device use
2. 30 mins to create RES™
3. Treatment area is 80x donor area



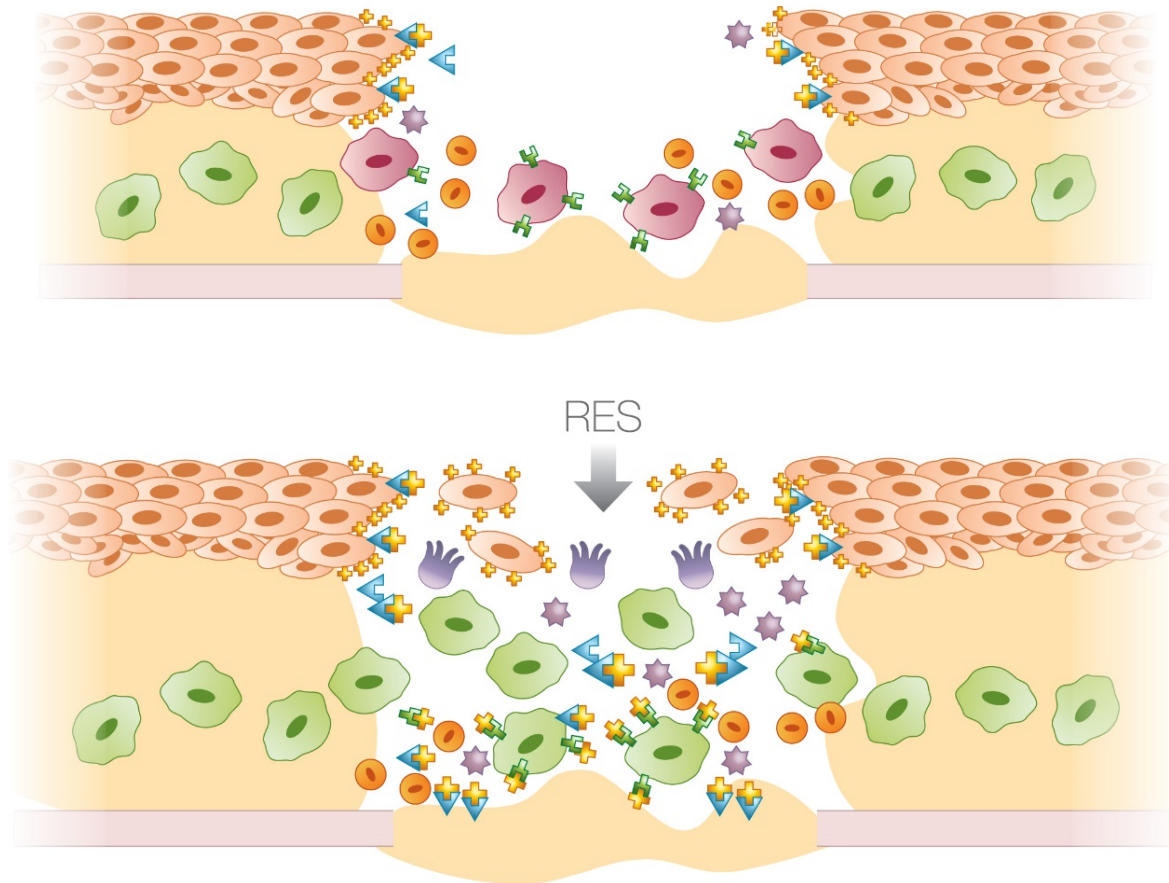
**Fast, Easy, Safe and Efficacious On-Site Skin Regeneration System**



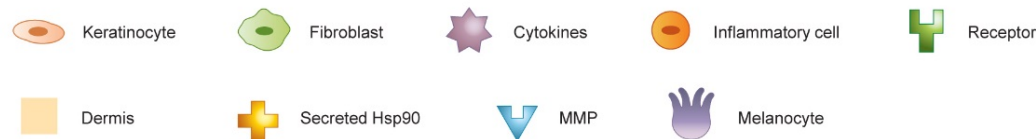
Wood et al. 2012. *Burns* 38:44.  
Singer & Clark. 1999. *NEJM*. 341 (10): 738.

**avita** medical  
transforming lives

# RES™ Mechanism – supplying skin cells



- Autologous samples derived from healthy areas of the skin contain a complete mix of all skin cells (non-cultured) and factors to catalyze the healing process
- Cells in suspension are no longer contact-inhibited by neighbouring cells (unlike intact tissue) and undergo phenotypic changes to promote closure (free-edge effect)
- Application of RES overcomes the usual limited availability of healthy, signalling cells



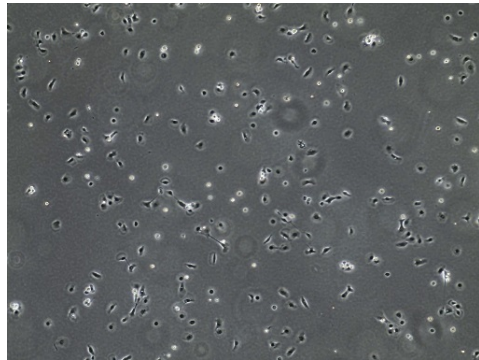
Trim & Quick. 2015 J Wound Tech 27:20-24.  
Singer & Clark. 1999. NEJM. 341 (10): 738.

Activated, Autologous, Available and Complete

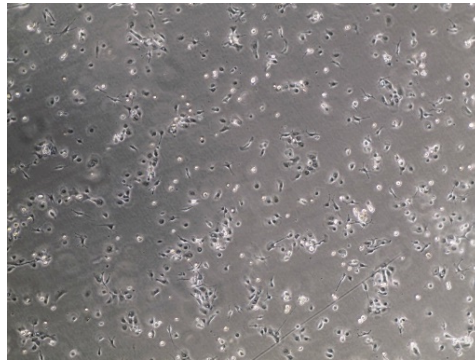
**avita**<sup>medical</sup>  
transforming lives

# RES™ Mechanism – “Activated”

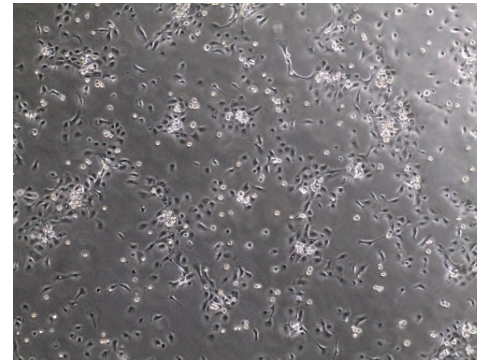
Keratinocytes from RES™ in a wound bed model after Autologous Cell Harvesting\*



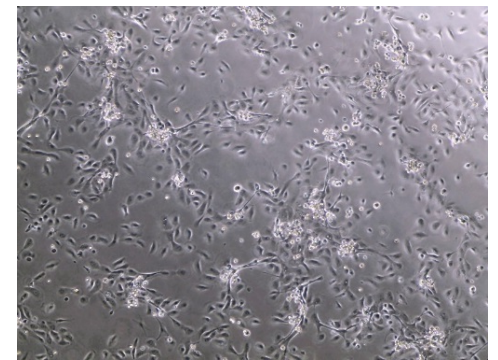
1 day



3 days

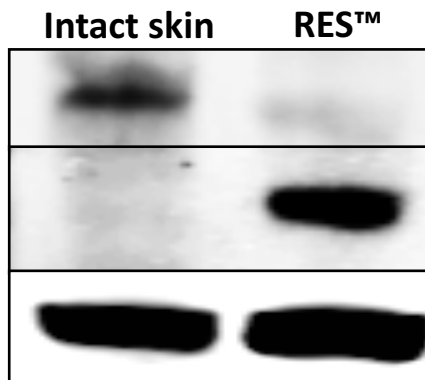


5 days



7 days

- Large numbers of viable skin cells in RES™ adhere to the wound bed almost instantly
- Proliferative and migratory morphologies can be seen as early as day 1
- *Rapid isolation and then immediate application to the ideal incubator, the human body, supports normal cell processes*



**Involucrin** is a signalling protein present in normal, intact skin.

When skin cells are in a healing (proliferative) state, involucrin expression decreases.

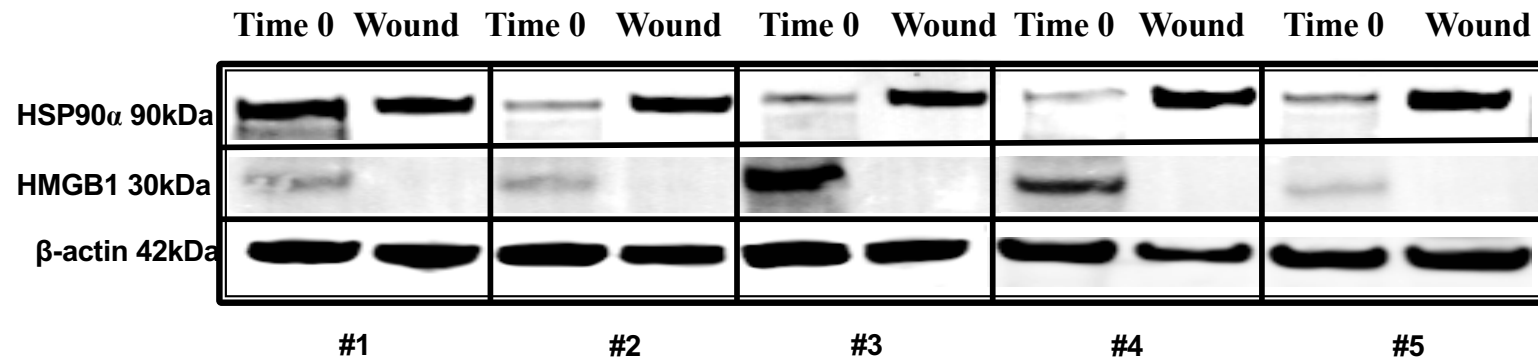
**P-ERK** is a signalling protein that is activated during skin cell proliferation, it plays a role in the coordination of repair. p-ERK increases during healing

**β-Actin** - Loading control

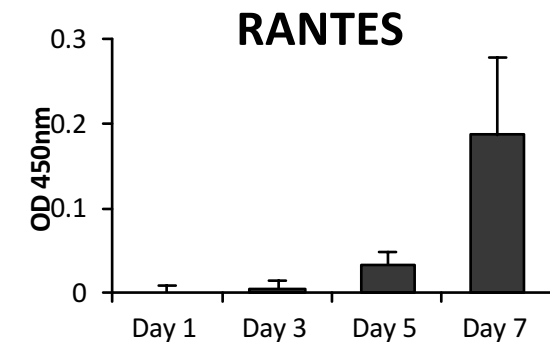
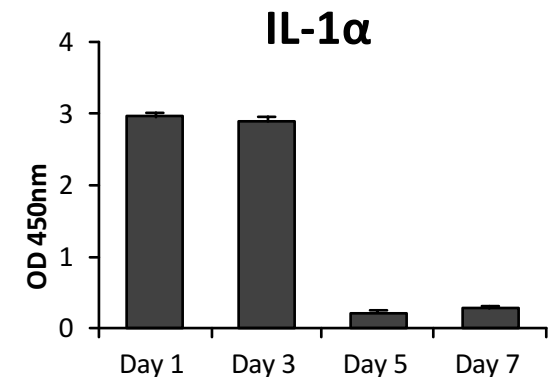
\*Representative specimens routinely isolated using ReCell® device at Huddersfield Skin Integrity Institute



# RES™ Mechanism – signaling for tissue repair



- Danger associated molecular patterns (DAMPs) – key to regulation of tissue repair
  - HSP90α and HMGB1 are naturally present in RES as a result of the cell harvesting process
- Secreted factors - also important in tissue repair
  - VEGF, EGF, RANTES, IL-1α, TNF-α – all confirmed present in RES™



# Clinical Evidence Base

- Early product approvals based on case series, 60+ presentations and publications to date
- More recently, pursuing robust, randomized controlled trials

Clinical Indication	RCT	Readout
Burns	ReCell adjunct to widely expanded autografts, for treatment of mixed-depth (incl. full-thickness) burn injuries (US, CTP001-6)	Full Clinical Data Package Complete Q1 2017
Chronic Wounds	ReGenerCell for treatment of hard-to-heal venous leg ulcers (UK, CTP003)	presented, 2016 EWMA
Chronic Wounds	ReGenerCell for treatment of chronic wounds (China)	published 2015, British J Surg
Aesthetics/ Repigmentation	ReNovaCell for repigmentation of segmental vitiligo/piedbaldism (Netherlands)	published 2015, J Amer Acad Dermatol; new publication in prep
Aesthetics/ Repigmentation	ReNovaCell for repigmentation of hypopigmented scar (Germany)	Published 2016, Burns (Journal of Int'l Society for Burn Injuries)

**Clinical Evidence Demonstrates Better Outcomes in Multiple Indications**





# ReCell® and Meshed Autograft – healing with less donor skin

- Treatment of large surface/deep burns ***with limited donor site usage***
  - Addresses unmet need in burn care
  - Designed for clinical effectiveness with minimal donor site requirement
  - Patient with 64% burn, hospital length of stay 0.58 days per % TBSA (vs  $1.9 \pm 0.7$  days for severity matched historical control)



Treatment  
**RES™ + Meshed Autograft**



1 Month post treatment

---

**Can reduce length of stay in large burns by over 50%**

---



Holmes JH. 2016 Biennial Meeting of the International Society for Burn Injuries, Miami, FL

**avita**<sup>medical</sup>  
transforming lives

## RES™ on a burn injury – excellent outcome



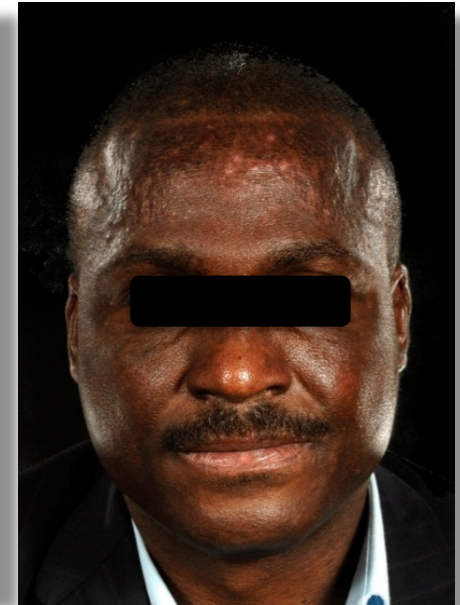
**Deep Partial Thickness Burn**



**Treatment: excision, and RES™**



**Post-operation, Day 9**



**Post-Operation, 4 months**

- Case Report: 48-year-old man, flame burn injury from an exploding boiler. Treated at Chelsea and Westminster Hospital
- Sub-optimal to use skin grafts on facial wounds
- Application of RES™ triggered wound healing
- Reintroduction of melanocytes clearly gives superior cosmetic outcome

**Achieving Healing and Normal Appearance**



Courtesy of Ms Isabel Jones, Chelsea and Westminster Hospital

**avita**<sup>medical</sup>  
transforming lives

# Autograft Sparing and Emergency Preparedness

---

- Great benefit is associated with use of less donor skin to achieve definitive closure and better long-term outcomes in burn care
- We are working to establish ReCell® as the **go-to** autograft-sparing technique, based on clinical and economic benefit
  - Autograft sparing reduces the burden on the already-injured patient faced with the harvesting of their healthy skin
  - Autograft sparing potentially reduces the number of procedures and overall length of hospital stay
  - The need for skin is a key bottleneck in mass response
- ReCell® is versatile, portable and self-contained



# The BARDA Contract

---

- A total of USD\$61.9m committed under the five-year contract awarded Sept 29
- BARDA is locked in to pay \$27.9m to complete the FDA-PMA process, ensure Avita is market-ready, and buy an initial inventory of more than 5,000 devices to be stockpiled
- BARDA also has options to spend \$34m more on larger procurement, and various strands of post-market entry support
- Avita is also engaged with other branches of the US Federal government: the device is portable, flexible and self-contained, and has great potential for military use
- Avita is now using BARDA funds to strengthen its operations and to develop clinical and economic data for the burns community in advance of a US launch



---

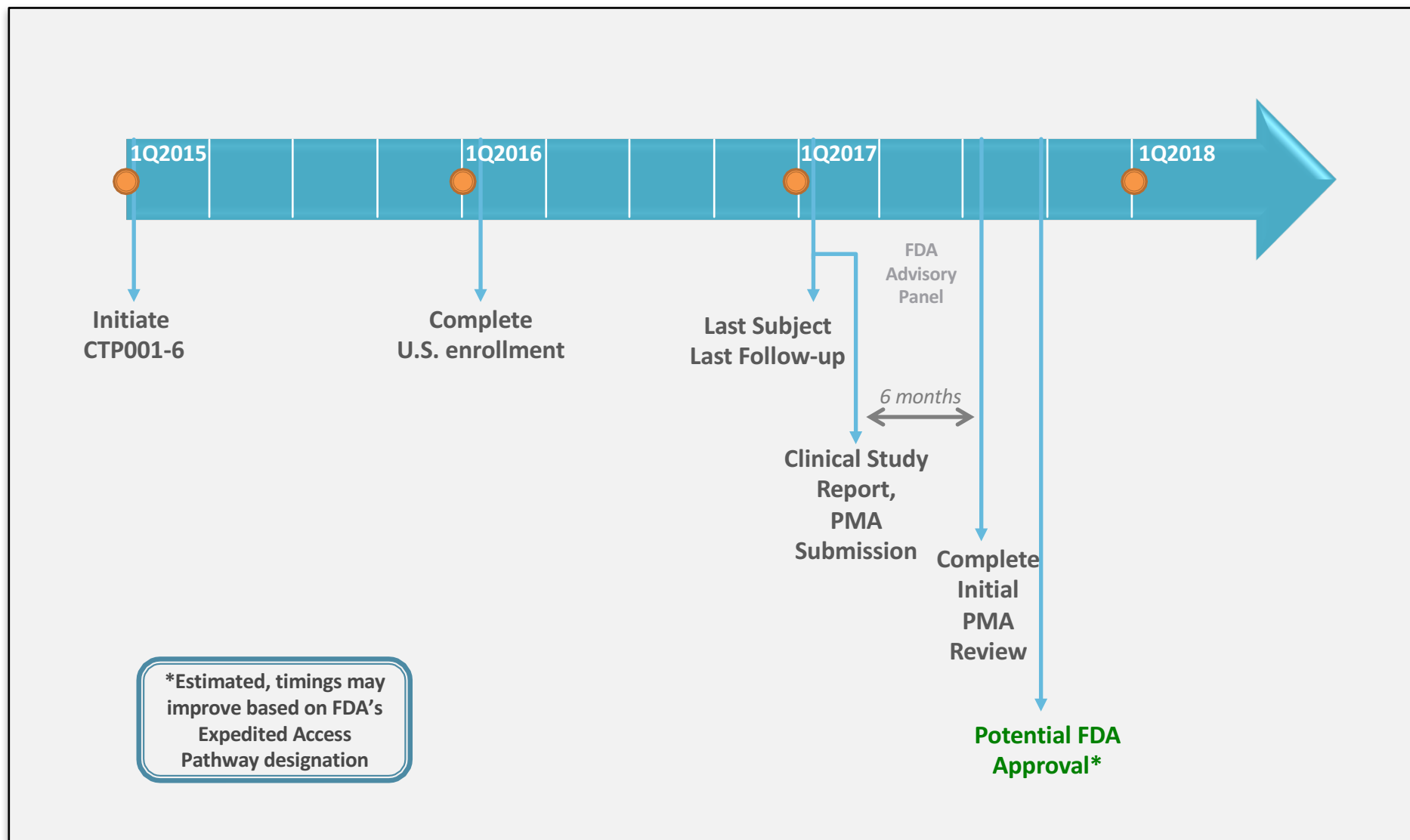
**BARDA adds resources and validation to Avita**

---





# Projected U.S. ReCell<sup>®</sup> Burns Approval: Q3 2017



# ReGenerCell™ - Closing Wounds where other routes Failed

**Case Study 1: 67 year old female with peripheral arterial disease, controlled type II diabetes**  
VLU (10 cm<sup>2</sup>) on right lateral malleolus open for 46 weeks before treatment with ReGenerCell.



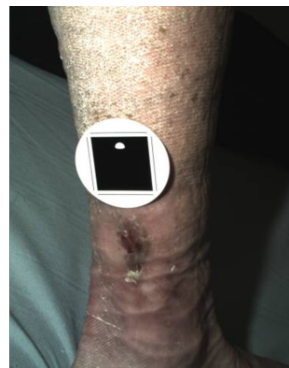
Baseline



Week 1



Week 6



Week 11



Week 13

***"[It's] just a miracle.  
Got my life back, can go  
out and socialise.  
Three years ago I  
couldn't walk 10 yards"***

**Case Study 2: 70 year old male with peripheral arterial disease, controlled type II diabetes. Right medial VLU (13 cm<sup>2</sup>) open for 212 weeks before treatment with ReGenerCell.**



Baseline



Week 1



Week 6



Week 10



Week 14

***"Changed within a month,  
could see the change,  
getting smaller and not  
so deep.  
Pain was reduced after the  
cells were applied,  
no pain at all after week 4"***

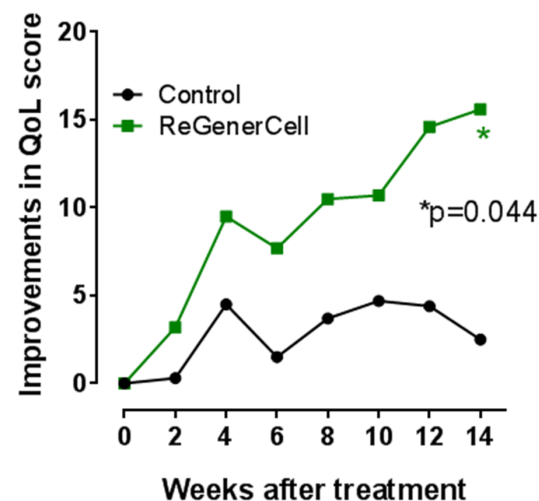
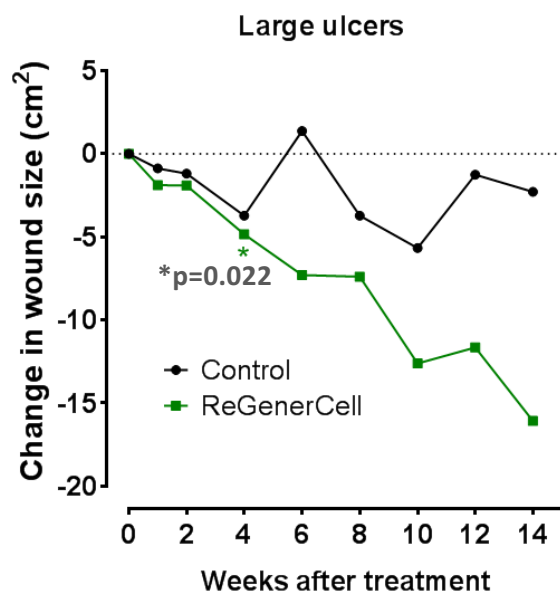


**avita**<sup>medical</sup>  
transforming lives



# ReGenerCell – venous leg ulcer pilot RCT highlights

- Statistically significant improvements shown in wound size, pain and health-related quality of life
- Positive trends both in healing time, incidence of closure and all aspects of the Quality of Life questionnaire were observed. This was of particular note in large ulcers (over 10 cm<sup>2</sup>) which comprise the majority of VLUs
- Treatment using ReGenerCell™ definitively places the wounds on a healing trajectory



# ReGenerCell™ for pre-tibial laceration



**Admission &  
Debridement**

**ReNovaCell  
applied after one  
week of  
conventional care**

**Three weeks after  
ReNovaCell  
treatment, 25%  
reduction**

**After five  
weeks, 75%  
reduction**

**After 11 weeks,  
100% healing**

- Case Study: an 85-year-old woman, suffered 8cm x 5cm gash on left leg. Treated at Kings College Hospital, London
- RES™ applied in an outpatient clinic
- Patient reported to be very satisfied with the outcome, which allowed her to maintain her independent lifestyle
- Pre-tibial Lacerations are a frequent problem for women aged over 60, and are challenging to treat

**Treatment Potential only now being Realized**



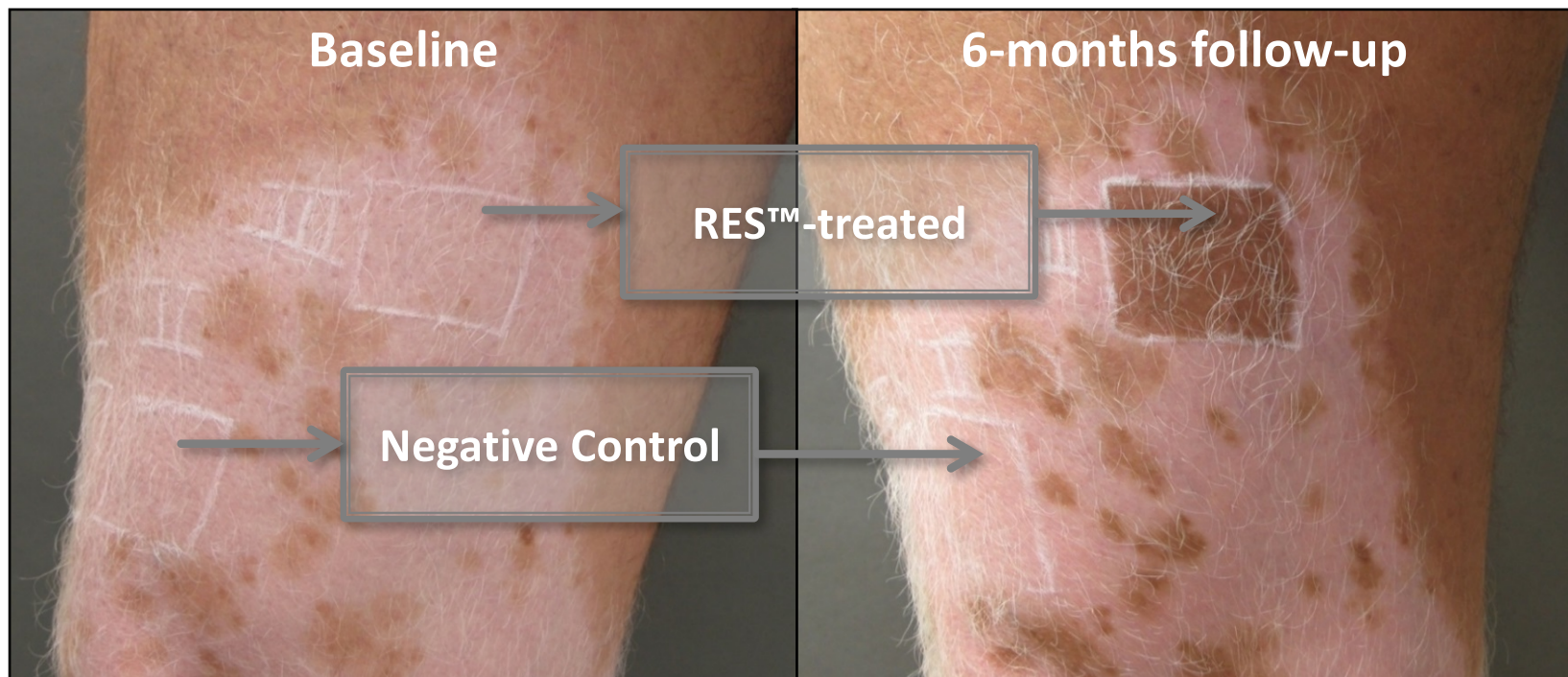
Courtesy of Dr Robert Manton, Charing Cross Hospital London

**avita**<sup>medical</sup>  
transforming lives

# ReNovaCell: Simple Solution for Skin Repigmentation

- Repigmentation of hypo-pigmented skin due to old age, injury, skin treatments, vitiligo
  - Most significant unmet medical need in aesthetic dermatology
- Current Inadequate Treatment Options for Repigmentation
  - Non-surgical options “lotions & potions” and light therapy sometimes efficacious
  - Lab-based melanocyte transfer is sole surgical choice but expensive, time consuming
- ReNovaCell is the only simplified, cost-effective solution for skin repigmentation

**From published RCT\*: patient with segmental vitiligo (duration > 5yrs)**



\*Komen L, Vrijman C, Tjin EPM, Krebbers G, de Rie MA, Luiten RM, van der Veen JPW, Wolkerstorfer A. Autologous cell suspension transplantation using a cell harvesting device in segmental vitiligo and piebaldism patients: a randomized controlled pilot study. J Am Acad Dermatol 2015; 73(1):170-172.

**avita**<sup>medical</sup>  
transforming lives



# Substantial Opportunity Treating Large, Complex Wounds

Selected Indications <small>e.g., excludes plastic and maxillofacial surgeries</small>		Incidence/Prevalence (Patients)				Percent Applicable	Potential Market Size (assume 1 device per patient)
		US <i>pop. 316M</i> (11.4% diabetes <sup>1</sup> )	UK, FR, DE, IT <i>pop. 271M</i> (8% diabetes, avg <sup>1</sup> )	Aus <i>pop. 23M</i> (5.1% diabetes <sup>1</sup> )	China <i>pop. 1.4B</i> (9.3% diabetes <sup>1</sup> )		
Chronic Ulcers	DFU <sup>2</sup>	9.0M	5.5M	0.3M	31.6M	20 – 40%	9 – 19M
	VLU <sup>3</sup>	3.2M	2.7M	0.2M	13.6M	60 – 65%	12 – 13M
Burns <small>annual admissions</small>		40K <sup>4</sup>	42K <sup>5</sup>	8.6K <sup>6</sup>	3.4M <sup>7</sup>	90%	3.1M
Aesthetics <small>annual procedures<sup>8</sup></small>		1.7M	585K	117K	157K	90%	2.3M
Vitiligo <small>0.1% to 2% of pop.<sup>9</sup></small>		316K	271K	23K	1.4M	30%	0.6M
<b>TOTAL*</b>		<b>14.3M</b>	<b>9.1M</b>	<b>0.7M</b>	<b>50.1M</b>	<b>35%-50%</b>	<b>~27-38M</b>

<sup>1</sup> International Diabetes Federation (IDF) Diabetes Atlas, Sixth Edition (2014)

<sup>2</sup> [Lifetime incidence: 25% of diabetics] Singh et al. "Preventing foot ulcers in patients with diabetes." JAMA 293, no. 2 (2005): 217.

<sup>3</sup> [Prevalence: 1% of pop.] Humphreys et al. "Management of mixed arterial and venous leg ulcers." Br. J. Surg. 94, no. 9 (2007): 1104.

<sup>4</sup> American Burn Association 2013 Fact Sheet ([www.ameriburn.org](http://www.ameriburn.org))

<sup>5</sup> Brusselaers et al. "Severe burn injury in Europe: a systematic review of the incidence, etiology, morbidity, and mortality." Crit Care 14 (5) (2010): R188.

<sup>6</sup> Australian hospital statistics. Australian Institute of Health and Welfare. (2012)

<sup>7</sup> Peck MD. Epidemiology of burn injuries globally [www.uptodate.com](http://www.uptodate.com)

<sup>8</sup> ISAPS 2013 International Survey on Aesthetic/Cosmetic Procedures Performed (dermabrasion, resurfacing, facial rejuvenation)

<sup>9</sup> 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.





# Translating clinical development to successful commercialization

---

- US Burns trial enrollment complete
  - Expedited Access Pathway (EAP) designation
  - Continued Access and Compassionate Use IDE Programs
- RCTs in other key areas either published or in prep for publication
- Mechanism of Action details further explored and in prep for publication
- Currently generating additional data in larger market opportunities (chronic wounds, aesthetics, etc.)
- Broadening and bolstering sales and marketing armamentarium with robust health economic analyses to show positive budget impact to both payers and providers
- Accelerating business development activities for indication-specific commercial partnering



**For more information**

**[www.avitamedical.com](http://www.avitamedical.com)**

