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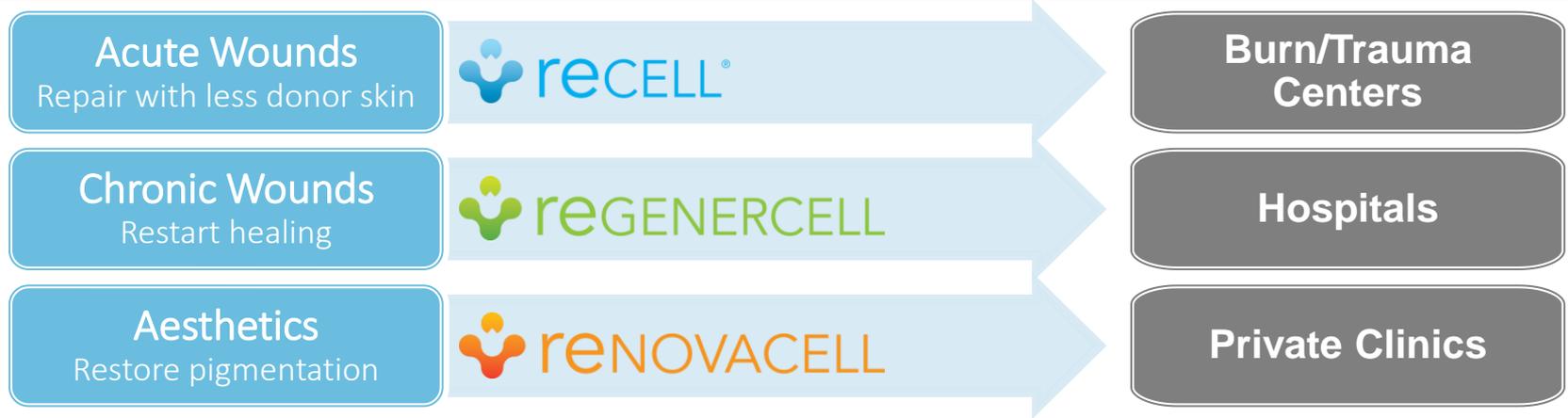
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# Avita Medical - Company Background



- Platform autologous cell harvesting technology addressing unmet need in clinical indications encompassing a range of skin injuries and defects
- Cleared for marketing in EU, Australia, China
- U.S. FDA Pivotal Trial for *burns* underway, expect complete recruitment end of 2015
- Publicly-traded in Australia (ASX:AVH) and US ADRs (OTCQX:AVMXY)
- Clinical, regulatory and financial operations in Los Angeles with commercial operations in UK and Asia

**A Global Pioneer in Regenerative Cell Therapy**



# Skin Regeneration Platform

- **Autologous cell harvesting device used to prepare Regenerative Epithelial Suspension (RES™) for treatment of 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 apply RES™
- **Rapid (30 min) preparation of RES™ at point of care**
  - Activated, autologous skin cells (keratinocytes, fibroblasts, melanocytes, including progenitor cells)
  - Signaling factors (cytokines, chaperones like hsp90, growth factors)
- **RES™ applied, often in combination with conventional techniques (with autografts, compression dressing, laser)**



***ReCell® is an investigational device in the United States, limited by US federal law to investigational use.***

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

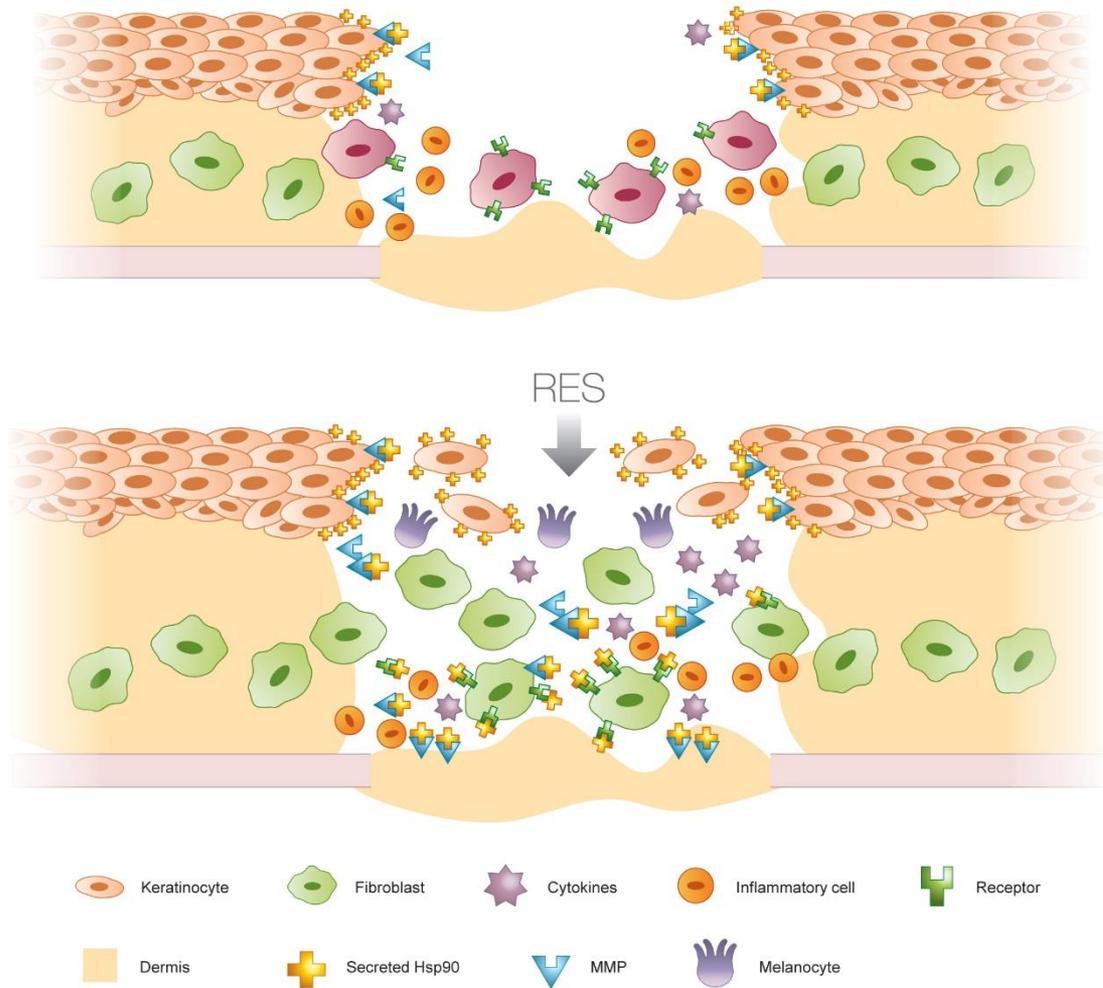
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Wood et al. 2012. *Burns* 38:44.



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# RES™ in Skin Regeneration



- Autologous samples derived from healthy areas of the skin contain a complete mix of all skin cells (non-cultured) and factors to catalyse 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**

# RES™ 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*
  - Addresses unmet need in burn care
  - Designed for clinical effectiveness with minimal donor site requirement



Pre-treatment  
Excised 3<sup>rd</sup> degree burn



Treatment  
ReCell + Mesh Graft



Week 14 post treatment



# ReCell<sup>®</sup> in Burns – Pediatric Scald



Before treatment



10 months post treatment

Living The Mission of Transforming Lives

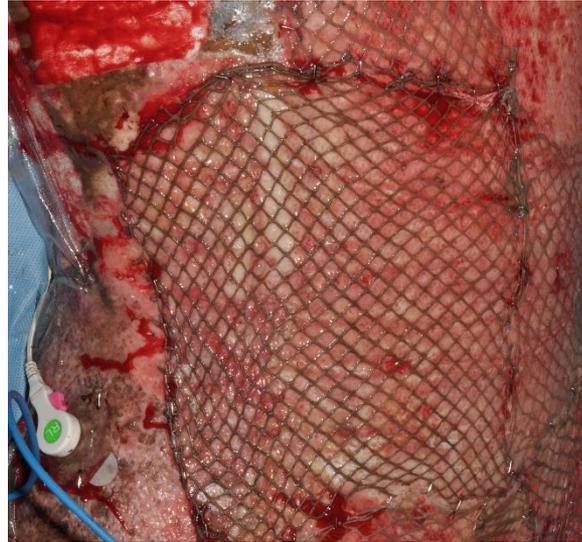


Courtesy of Jeremy M Rawlins FRCS(Plast)

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# Massive Burn Injuries

- 19-y/o male, 75% TBSA (60% deep partial to full-thickness)
- Treated under Compassionate Use, with RES™ and meshed autograft expanded 1:6



6 months post treatment

## Significance:

**Autograft donor skin spared: 1,025 cm<sup>2</sup> (5% TBSA)**

**Definitive closure after 4 operations, vs 6-7 institutional average**

**Length of stay: 1.3 days per %TBSA, vs 2-3 days per %TBSA institutional average**

*Presented by Holmes, JH at the 17<sup>th</sup> Congress of the International Society for Burn Injuries (2014)*



# Autograft Sparing and Emergency Preparedness

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- 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<sup>®</sup> 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<sup>®</sup> is versatile, portable and self-contained



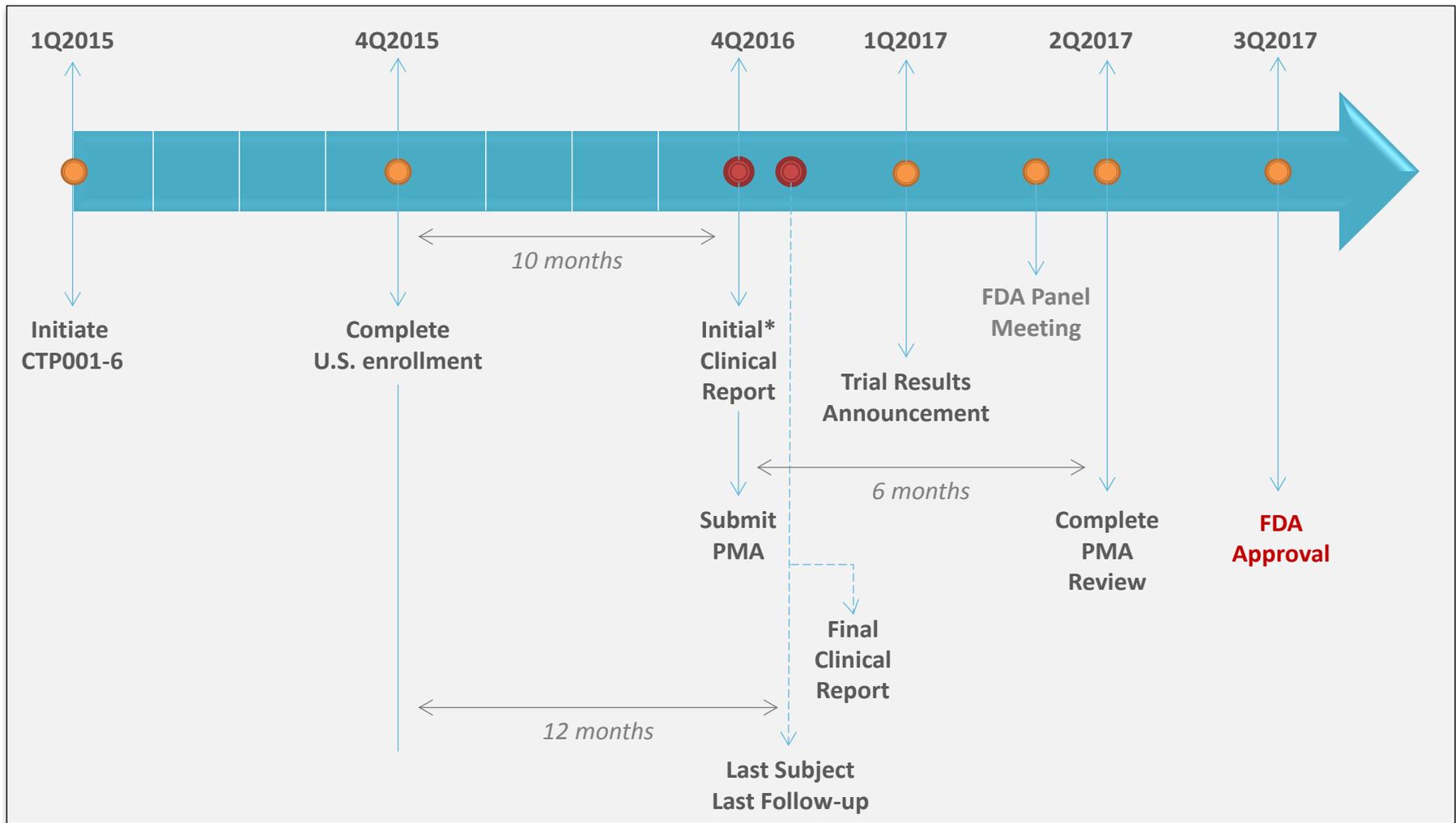
# BARDA – HHS Office of the Assistant Secretary for Preparedness

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- RES™ history in Mass Casualty Events
  - Bali bombing (2002)
  - Ashmore reef (2009)
  - Taiwan water park (2015)
- BARDA contract announced Sept 29, valued up to \$54m
  - Clear recognition of ReCell®'s potential for burns treatment in a mass casualty event
  - The funding awarded will support Avita through FDA PMA, and establishes vendor-managed inventory for 5,000 - 25,000 devices
    - Contract options allow for support of post-mark surveillance (CoA) and paediatric studies as needed.



# Projected U.S. ReCell<sup>®</sup> Burns Approval Timeline



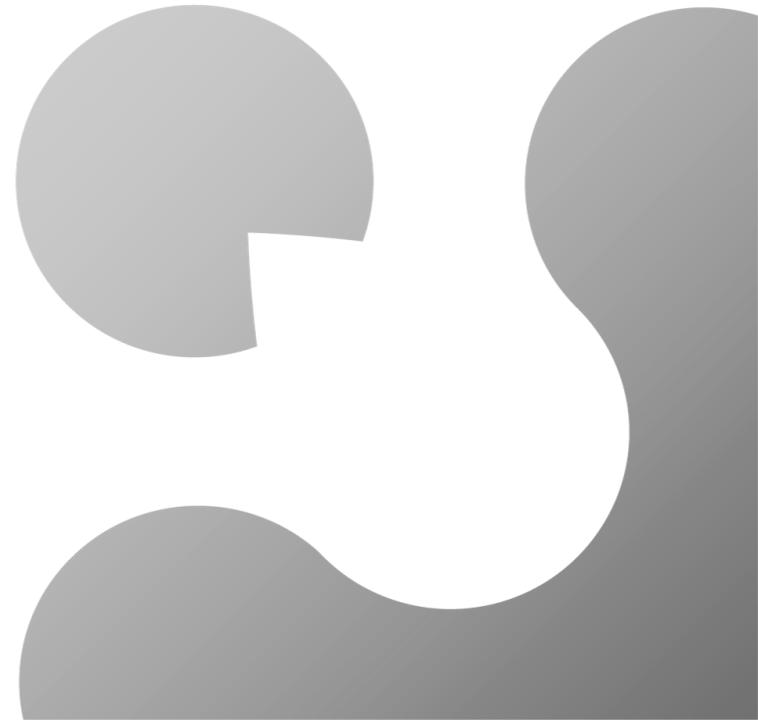
\*Complete effectiveness data & interim (9-month) safety data



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# The AVITA Opportunity

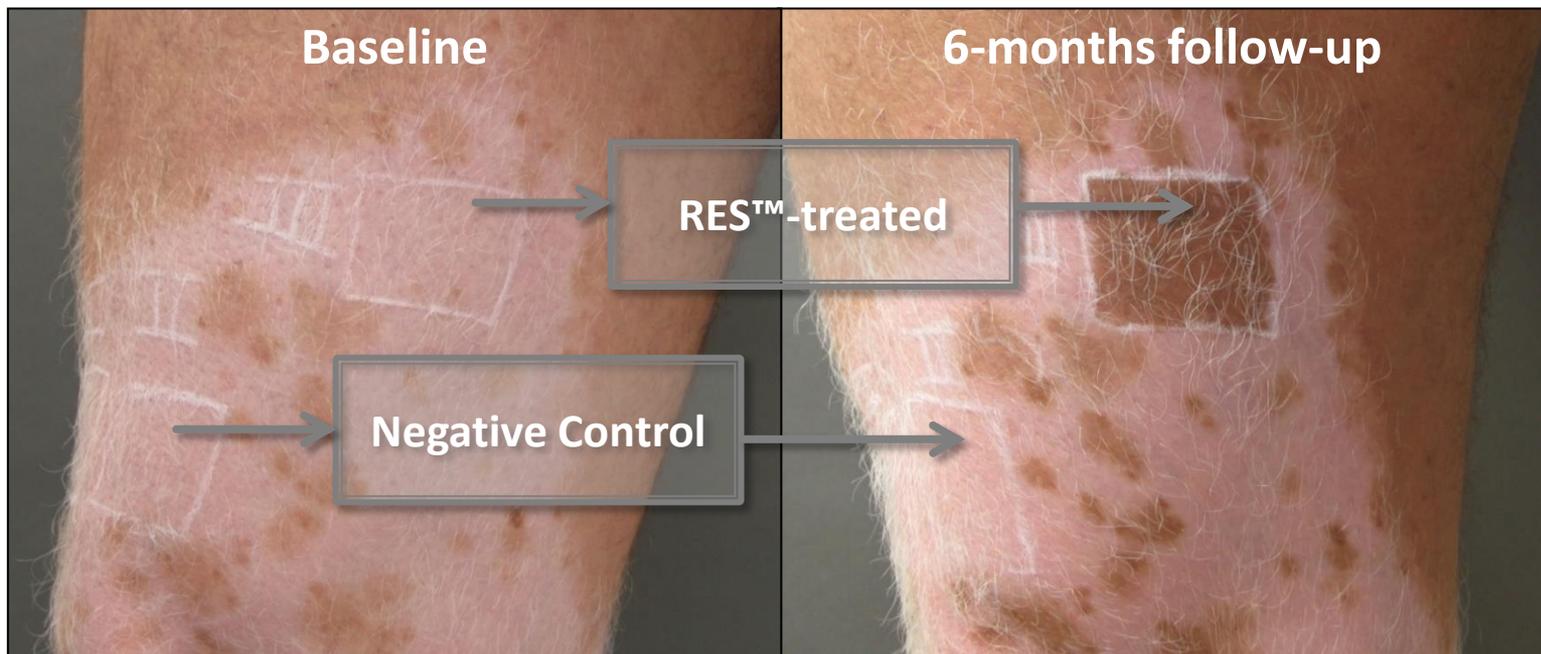
## Beyond Burns



# 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
  - 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.



# ReGenerCell Can Achieve 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 before treatment using ReGenerCell.



**Baseline**  
VLU area = 55cm<sup>2</sup>

**RES**  
**Treatment**



**Week 7**  
VLU area = 8cm<sup>2</sup>  
% Re-epithelialization vs baseline=  
85%



**Week 20 (5 mo)**  
VLU area = 2cm<sup>2</sup>  
% Re-epithelialization vs baseline=  
96%



# 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.



# Partnering to Maximize Commercial Strategy

- **2015: a watershed year in clinical strategy and product approval**
  - Broadened ex-US approvals; launch newly-branded products
  - Initiated FDA pivotal trial in burns; completion of enrollment expected 2H '15
  - Ongoing European RCT trials in VLU
- **Commercial strategy through corporate partnerships is the next focus**
  - Strategic deals by indication/call point/geography



## AVH: "To do" list

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



*illustration purposes only*

**Sufficient Progress to Attract Strong Corporate Partners**



# Summary

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- Leader in regenerative, cellular therapy for treating skin defects
- Multiple commercial products address ~\$15 billion WW complex wound and dermatology markets
- Differentiated by superior clinical data and compelling value proposition
- Extensive global patent portfolio provides strong barriers
- Management team with track record of commercial execution

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**In the Right Space, With the Right Products, at the Right Time**

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**For more information**

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

