

## **Equity Raising Presentation**



October 2017

## 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.

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## **Capital Raising summary**

Overview	
Transaction	Placement of approximately 101.0 million new fully paid ordinary shares ("New Shares") to raise approximately A\$4.5 million in accordance with ASX L.R 7.1 (the "Placement") and an underwritten non-renounceable entitlement offer to raise approximately A\$12.4 million (the "Entitlement Offer") (together the "Offer").
Lead Manager & Underwriter	Bell Potter Securities Limited
Last Close Price	A\$0.085
Offer Price	A\$0.045 per share (33.6% discount to 30 day VWAP)

Offer	
Placement	Placement of New Shares at A\$0.045 per share to raise approximately A\$4.5 million. The Placement will be conducted under the 15% placement capacity of the Company in accordance with ASX L.R 7.1.  New Shares under the Placement will rank equally with existing ordinary shares.  The Placement will be on a cum-entitlement basis.
Entitlement Offer	Fully underwritten 1 for 2.8 pro rata non-renounceable entitlement offer to raise approximately A\$12.4 million. The Entitlement Offer price will be A\$0.045 per share. The Record Date for the Entitlement Offer is expected to be Wednesday, 18 October 2017.





## Capital Raising: Indicative timetable

Indicative Timetable	
Trading Halt	Monday, 9 October 2017
Book closes for receipt of firm and irrevocable bids in Placement	12:00pm (Sydney time), Tuesday, 10 October 2017
Placement and Entitlement Offer announced, Entitlement Offer booklet with ASX and company resumes trading	Before 9.30am (Sydney time), Wednesday, 11 October 2017
Letter sent to Shareholders advising of Rights Issue Appendix 3B information and timetable	Friday, 13 October 2017
'Ex' date for the Entitlement Offer	Tuesday, 17 October 2017
Record date to determine entitlements under the Entitlement Offer	Wednesday, 18 October 2017
Entitlement document dispatched to shareholders and Entitlement Offer opens	Friday, 20 October 2017
Entitlement Offer closes	Thursday, 2 November 2017
Entitlement Offer securities quoted on a deferred settlement basis	Friday, 3 November 2017
Settlement of Entitlement Offer	Wednesday, 8 November 2017
Allotment of New Shares issued under the Entitlement Offer. Deferred settlement trading ends.	Thursday, 9 November 2017
Dispatch of holding statements in respect of New Shares issued under the Entitlement Offer	Friday, 10 November 2017





## **Capital Raising: Structure**

Structure	
Total number of Shares currently on issue	673,219,854
Total number of shares to be issued under the Placement	100,982,978
Expanded issued capital post Placement	774,202,832
Rights ratio	2.8x
Total number of shares to be issued under the Entitlement Offer	276,501,011
Total number of Shares on issue at Completion of the Offer	1,050,703,843





## Capital Raising: Use of Funds

\$A16.9m equity raising will ensure the Company is fully funded to complete and advance its near term objectives, and provide balance sheet flexibility

#### **Use of Funds**

- US Commercialisation: headcount, sales & marketing initiatives;
- R&D to explore expanded indications;
- Market specific local clinical trials / studies;
- Market specific Health Economic & Pricing studies;
- Purchase of materials to fulfil the ~USD\$7.6m initial procurement order from BARDA;
- Product Development initiatives; and,
- Additional working capital





## Market Update

### Recent milestones highlight a significant shift in Company fundamentals

October

U.S. FDA Approves New Continued Access Protocol for ReCell

September

- Submission of U.S. FDA PMA Application for ReCell
- Avita Medical and BARDA Execute a US\$24.3m Contract Option
- Positive US Study results presented at European Conference

August

Avita Medical names Erin Liberto as Chief Commercial Officer



for further details please visit www.asx.com.au



### **Overview**





## **Avita Medical Company Overview**

- Regenerative medicine platform company
- Proprietary autologous spray-on skin
- Initial focus on \$5.7B U.S. burns market
- U.S. pivotal study complete
  - Met co-primary endpoints
- PMA submitted Q3 '17
  - FDA Advisory Committee TBD
  - U.S. approval anticipated Q2/Q3 '18
- \$61.9M BARDA contract funds:
  - PMA and pediatric studies
  - Emergency Use Authorization,
     Compassionate Use, Continued Access,
     and training & education

- Operations based in Australia, UK, USA
- Tickers: ASX:AVH; OTCQX:AVMXY



- \$8M in revenues pre US approval (\$1.18M commercial / \$6.6M from BARDA contract)
- CE mark issued in 2005; approvals in 33 countries
- Future Pipeline Markets
  - -Chronic Wounds (VLU & DFU)
  - –Aesthetic Dermatology / Plastics





## De-Risked Significant Near-Term Value Drivers

### Elements required for rapid commercial adoption are in-place

- U.S. Pivotal study co-primary endpoints achieved; FDA PMA approval expected Q2/Q3 '18
  - Rapid U.S. adoption projected based on compelling clinical and health economics data
    - 3 Device safely used 7,000+ times, and already embraced in major U.S. burn centers
    - 4 Attractive financial opportunity with 85%+ gross margins anticipated
  - 5 Strong intellectual property; 10 issued patents and 18 pending
- 50+ supporting peer-reviewed journal publications



A Company Poised for US Market Entry in 2018



## Senior Leadership Team

### A Management Team with a Track Record of Success

Management Team		
Name	Years Exp.	Affiliations
Dr. Michael Perry CEO	30	NOVARTIS  Baxter  Schering-Plough BAY CITY CAPITAL ##
Tim Rooney CFO	25	rdi i EcoStrip
Erin Liberto CCO	16	Johnson Johnson Allergan
Andrew Quick Sr VP, Clinical Development	21	sonova Scientific
Ross Saunders VP Sales & Marketing	20	Johnson-Johnson ETHICON
David Fencil VP, Global Operations	30	QUALLION  Alfred Mann Foundation

Board of Directors		
Name	Years Exp.	Affiliations
Lou Panaccio Chairman	30	SONIC SENERA biosystems
Jeremy Curnock Cook	40	BioScience Managers EXCALIBUR
Dr. Michael Perry	30	NOVARTIS  Schering-Plough  BAY CITY CAPITAL ##
Louis Drapeau	45	InSiteVision a SUN PHARMA company
Damien McDonald	25	LivaNova  O DANAHER  MERCK
Prof. Suzanne Crowe	24	Burnet Institute AlfredHealth



A Seasoned Board that is Aligned with Management



## **Market Opportunity**



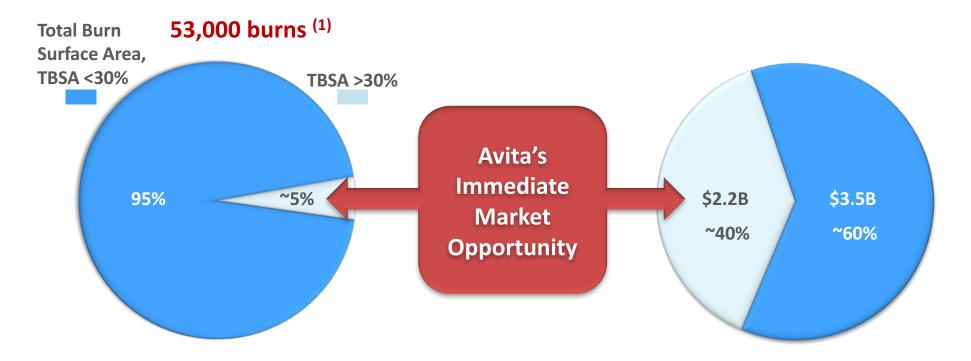


## U.S. Burns Market – Our Core Near-term Opportunity

### Large burns are an ideal initial market for ReCell®

**U.S. Burns Distribution by %TBSA** 

U.S. Burns: a \$5.7B Opportunity<sup>(2)</sup>



<sup>(2)</sup> ABA 2016 National Burn Repository weighted by the 53K hospitalized burns by TBSA % mean cost



Large Burns Cost an Average of ~\$770K Per Patient



<sup>(1)</sup> Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013, and Nationwide Emergency Department Sample (NEDS), 2013

## Burns Market – Significant Unmet Needs Remain

### Current therapies often deliver painful and/or expensive sub-optimal outcomes

**Current Standard of Care** 

Skin Graft (Used in 75% of Cases)

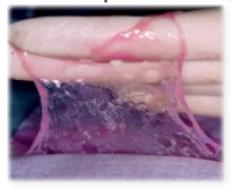




#### **Key Shortcomings**

- Large donor area required
- Pain (during and post procedure)
- Extended hospitalization & associated costs
- Multiple complex, costly, surgical procedures
- Infection

#### **Cultured Epithelial Autograft (CEA)**



#### **Key Shortcomings**

- Expensive
- Cosmesis (sub-optimal/poor)
- Extended Hospitalization
- Multiple complex, costly, surgical procedures
- Treatment time
- Risk of rejection



A Different Approach is Needed



### **Our Breakthrough Approach**





### A Unique Skin Regeneration Platform







### **Device Highlights**

- 1. Easy to use
- 2. 30 mins to treatment
- 3. Treatment area is 80x donor area

- An Autologous Cell Harvesting Device that uses a proprietary enzyme formulation to create a spray-on skin replacement in 30 minutes
- Single-use disposable; battery-powered and ambient-storable
- Designed by surgeons: an elegant means to address the complexities of epithelial closure
- Targeted to a well-defined group of clinicians; for use in a controlled clinical setting
- 7000+ uses to date in multiple world markets with no safety signals observed
- Ease of Use modest learning curve

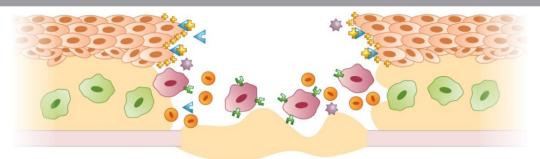


Safe, Fast, Simple, and Effective

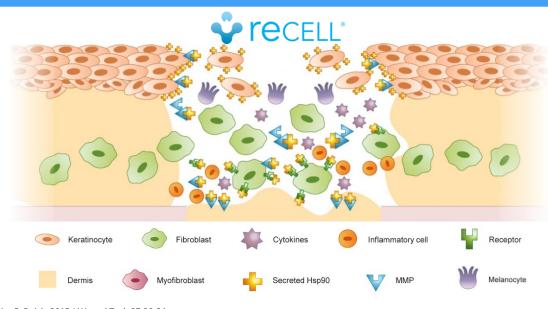


## Mechanism Of Action – Well Understood; Clinically Validated

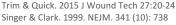
#### **Healing Process Without ReCell**



#### **Healing Process With ReCell**



- Small autologous samples derived from healthy areas of the skin
- Cellular suspension triggers a healing cascade across an entire wound bed
- Application of cellular suspension overcomes the usual limited availability of healthy, signaling cells
- Key skin cell phenotypes are delivered to facilitate optimal healing





Cell Suspension from ReCell Induces a Multi-Factor Healing Cascade



## Donor Site Comparison for 2<sup>nd</sup>-degree Burn Treatment

### ReCell uses dramatically less skin versus Autograft

ReCell vs Autograft (SoC)



Implications of Reduced Donor Size











Donor skin harvesting increases morbidity, creating secondary wounds for patients in already compromised condition, adding risks of donor site pain, itching, nonhealing, infection, and eventual unsatisfactory cosmetic appearance. In cases of extensive burn injuries, more efficient use of donor skin can translate to life-saving benefit.

Smaller and Shallower Donor
Site



**Reducing Donor Site Size is a Major Focus in Burn Centers** 



### **ReCell U.S. Pivotal Clinical Trial Results**





## Managing Risk within the US Regulatory Pathway

### **Consistent engagement with FDA**

FDA Engagement on Pivotal Study Design	
Jun '14	Avita/FDA meeting re: proposed design for pivotal trial
Aug '14/ Sep '14	IDE submission (Aug) and FDA IDE approval (Sep) of investigational plan
Jun '15/ Jul '15	Statistical Analysis Plan submission (Jun) and FDA approval (Jul)

FDA Engagement on ReCell (highlights)	
Feb '14/ Apr '14	Compassionate Use IDE submission (Feb) and FDA approval (Apr)
Sep '15/ Dec '15	Expedited Access Pathway (EAP) designation request (Sep) and FDA grant (Dec)
Sep '16	Pre-Emergency Use Authorization submission (by BARDA)

The EAP process of engaging interactively with FDA on PMA Data Development, Annual IDE progress reporting (for both compassionate use and CTP001-6) and FDA's review of the pre-EUA submission for ReCell has afforded the agency substantial insight into ReCell.



Agency expectations are clear and PMA will align



## U.S. FDA Pivotal Trial Design

### Confirmatory design based on prior ReCell studies and clinical experience



3<sup>rd</sup>-degree burn treatment ReCell + Meshed Graft



Week 14 post treatment

#### Sample Size: 25

Enrollment (N): 30

Randomized: 1: 1

Centers: 7

Age: ≥5yrs

Burns requiring skin grafts (2nd & 3rd degree)

% Burn: 5-50% TBSA

#### **Active Arm**

RES™ with widely meshed autograft

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

**Control Arm** 

Conventionally meshed autograft

#### **Co-Primary Endpoints:**

- 1. Expansion ratio<sup>(1)</sup> at time of treatment: Superiority\*\* of ReCell / Mesh combo versus graft alone
- 2. Complete closure rate at 8 weeks\*: Non-inferiority of ReCell / Mesh combo versus graft alone

(1) Donor area: Treatment area



#### A Randomized Controlled Multi-Center Trial

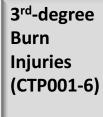


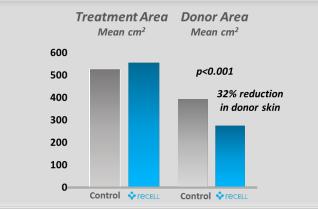
<sup>\*</sup>Additional procedures aiding wound closure allowed within initial 8 weeks;

<sup>\*\*</sup> ReCell expansion ratio: control expansion >1

## Autograft-Sparing Results Expected to Drive Adoption

### US Trial data demonstrate clinical and statistical superiority of ReCell in burn care

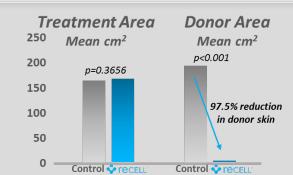




For 3<sup>rd</sup>-degree burn injuries, ReCell is used in combination with autografting expanded more widely than convention.

This approach yields a **32% reduction in skin** harvesting for the patient.

2<sup>nd</sup>-degree Burn Injuries (CTP001-5)



For 2<sup>nd</sup>-degree burn injuries, ReCell is used as an alternative to conventional autografting.

The use of cell suspension from ReCell in lieu of autografting yields a *97.5% reduction in skin harvesting for the patient*.

Taken together, the data confirm use of less skin harvesting without compromising healing or scar outcomes.



**ReCell Proven to Significantly Improve SOC Skin Grafting** 



## Pivotal Data Builds on Large Body of Supportive Evidence

### Avita possesses an unrivaled quantity and quality of clinical data

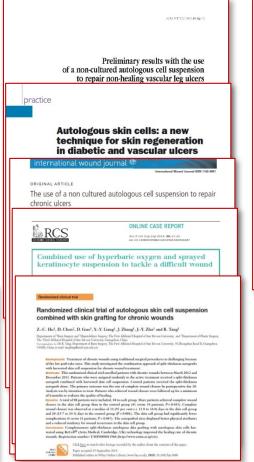


Burns

#### **Plastics**



#### Chronics



#### Repigmentation



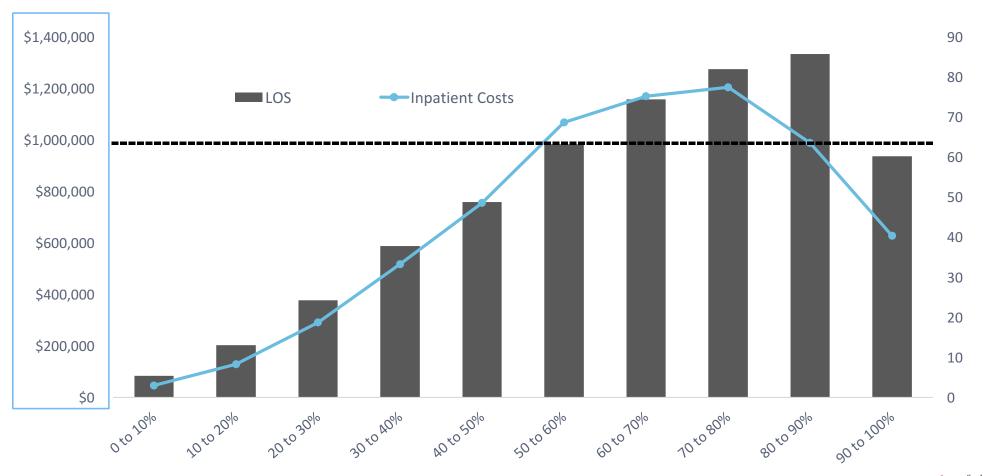


50+ Peer-Reviewed Journal Article Publications



## Large Burns Patients Impose A Significant Cost Burden

### Length of Stay (LOS) and Cost of Burn Patients Treatment<sup>(1)</sup>





**Large Cost Impact Provides Entry Point Into Hospitals** 



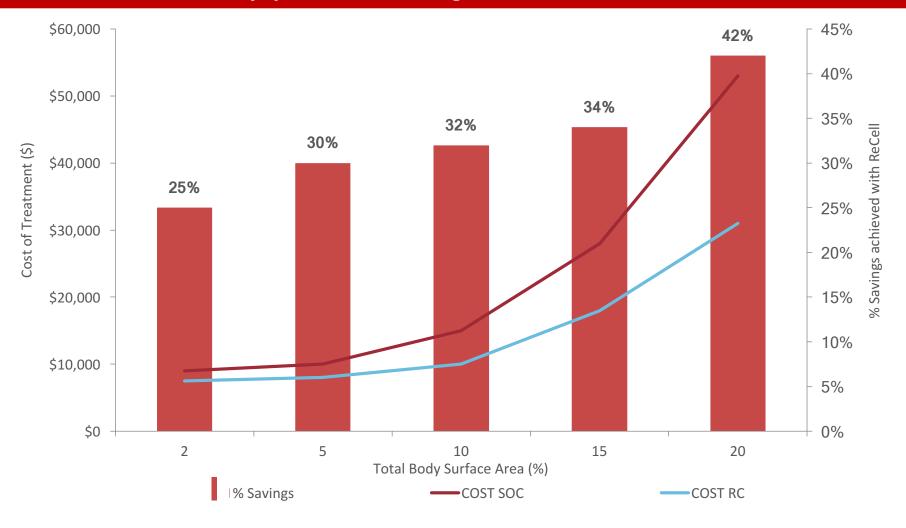
### **ReCell Health Economics**





## Highly Favorable Health Economics For ReCell vs. SoC

### ReCell enjoys a cost advantage vs. SoC across all burn sizes





#### **Better Outcomes At A Lower Cost**



## Case Studies Validate ReCell's Dramatic Cost Advantage

### ReCell is validated across the burn TBSA spectrum

#### **Case Study: Wake Forest**

- Wake Forest Baptist Medical Center
- 11 adults with median of 63% TBSA<sup>(1)</sup>
- Mean burn patient cost: \$3k per day; 2X avg. patient cost<sup>(2)</sup>
- Average expected based on historical data 119 days
- ReCell treatment shortened avg. stay to 71 days on average
  - √ 42% reduction in length of stay<sup>(2)</sup>
  - √ \$1.6M savings to the hospital
  - ✓ Or \$143K savings per patient

### **Case Study: Pinderfields**

- Evaluation at UK Pinderfields hospital showed up to 42% savings in >20% TBSA burns
- Similar findings in US burn centers, where the costs basis is higher, and the savings greater
- Shortened acute surgery duration<sup>(3)(4)</sup>
- Reduced length of stay<sup>(4)</sup>
- Reduced donor site morbidity
- Better functional and aesthetic scar outcomes

l) Park et al. 2013. Does the type of skin replacement surgery influence the rate of infection in acute burn injured patients?





<sup>(1)</sup> Holmes JH, Molnar JA, Craig CK, Williams JW, Carter JE. The Compassionate Use of ReCell in Treating Major Burns: A Single-center U.S. Experience Presented at: ANZBA: Oct. 2016 Auckland. NZ

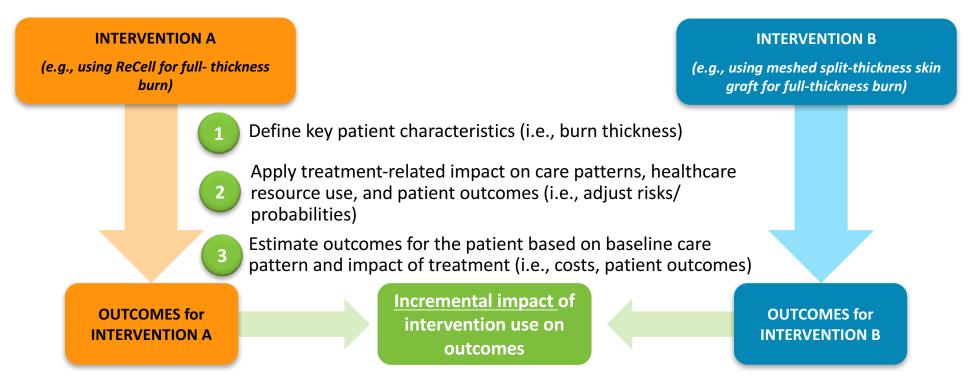
<sup>(2)</sup> https://www.hcup-us.ahrq.gov/reports/statbriefs/sb217-Burn-Hospital-Stays-ED-Visits-2013.jsp at Wake Forest the average stay per TBSA decreased from 1.8 days per every 1% TBSA to 1.1 days resulting in the 42% reduction in LOS

<sup>3)</sup> Lim et al. 2013. Is the length of time in acute burn surgery associated with poorer outcomes?

### **Health Economics Model**

# Avita with QuintilesIMS and BARDA support have developed a novel, robust, simple-to-use HE model that determines cost savings to burn centers

- The cost-effectiveness model of the acute burn care pathway uses sequential decision trees, accompanied by a budget-impact model with a comparative cost determination framework
- The model incorporates data from multiple interviews with burn surgeons, burn hospitals and from a targeted literature review of burn care data from the last 20 years





Most Robust Health Economics Model to date for Burns



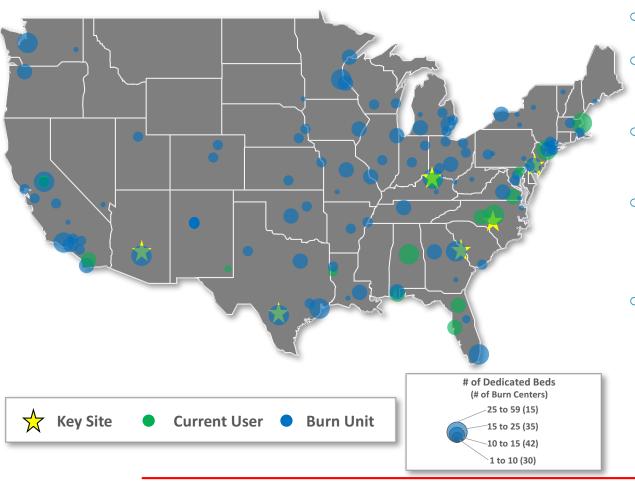
### **U.S. Commercialization Strategy**





## Avita – Already Well Established in Major U.S. Burn Centers

### The highly concentrated call points of the U.S. burns sector will aid rapid adoption



- 127 burn centers in the U.S.
  - 7 major U.S. burn centers in Pivotal Study
- 16% of U.S. burn centers have experience with ReCell
- FDA has approved increased enrollment for compassionate use four times (up to N=68)
- Ongoing Compassionate Use and Continued Access cases

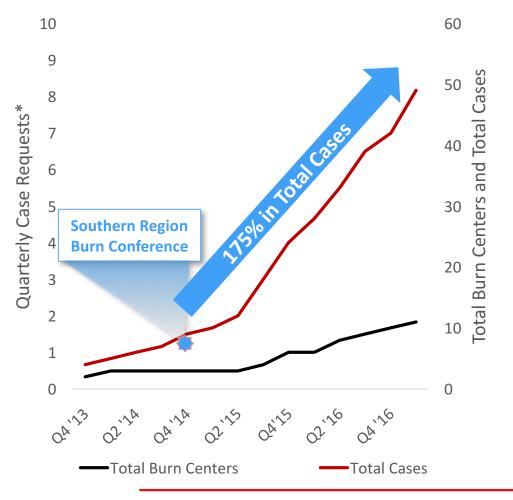


Compassionate Use is Granted in 20 Leading U.S. Burn Centers



## U.S. Compassionate Use – Indicator Of Adoption

The strong growth of FDA compassionate use requests across all U.S. regions demonstrates a clear unmet need and potential for rapid adoption



- Growth attributed <u>only</u> to peer-to-peer communication
- Product routinely in use for significant adult and pediatric burn injuries at major burn centers including:
  - AZ Burn Center (Phoenix)
  - Eskenazi Health (Indianapolis)
  - Wake Forest (Winston-Salem, NC)
- FDA has approved repeated requests for increased numbers of allowed cases without question



Seeding the US Market through Compassionate Use



**Regenerative Medicine Platform - Clinical Pipeline** 





## A Robust Regenerative Medicine Platform

Long-term value creation will be delivered by a platform technology applicable to multiple large markets

1

### **Major Burns**

- Market Opportunity: \$2.2B U.S. Market
- PMA approval expected Q2/Q3 2018
- Ongoing experience via Continued Access & Compassionate Use

2

#### **Smaller Burns**

- Market Opportunity: \$3.5B U.S. Market
- Pivotal trial included smaller burns (5% TBSA)
- Upcoming Pediatric trial funded by BARDA

3

**Chronic Wounds** 

**VLU** 

- Market Opportunity: \$1.0B U.S. Market
- Pilot VLU study complete; pub submission Q2 '18
- Phase 2 Study will be initiated in 2018



# Aesthetic Dermatology

- Market Opportunity: >\$10B U.S. Market by 2020
- Significant unmet medical need in dyspigmentation
- Non-segmental Vitiligo study commenced



**Targeting a Multi-Billion Addressable Aggregate Opportunity** 



### **Conclusions**



**Bringing Innovative Solution to Severely Underserved Burns Market** 



**Compelling U.S. Pivotal Data Demonstrate Effectiveness and Clinical Utility** 



**Health Economic Data Underscore Cost Savings for Burns Centres** 



PMA Approval Anticipated in 2Q/3Q '18 followed by Robust Commercial Strategy



**Attractive Pipeline Opportunities Ahead Leverage Our Technology Platform** 



**Management with Deep Expertise Paired with Commercial Success** 



**Platform Regenerative Medicine Company Primed for Rapid Growth** 



## For more information

www.avitamedical.com

