

AVITA Medical

Dr. Mike Perry, CEO

April 2020



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Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations.

AVITA’s products are Rx only. Please reference the Instructions for Use (www.avitamedical.com) for more information on indications, contraindications, warnings, precautions and adverse events.

In the United States, RECELL is approved for use in patients 18 years and older suffering acute thermal burns. Use of RECELL in other patient populations is either prohibited by United States law or may be made available pursuant to a relevant investigational device exemption granted by the FDA (and likewise limited by United States law to investigational use only).

AVITA Medical: Transformation Through Regeneration

Spray-On Skin™ Enables Skin Regeneration

RECELL harnesses the skin's own regeneration capabilities

- Standard of care enabling technology
 - **Donor skin-sparing + activated mechanism + point-of-care**
- Deep scientific and clinical pedigree
 - **2 RCTs and 1st PMA in burns in > 20 years**
 - 8,000+ patients, 50+ publications
 - U.S. FDA approved for acute burns*
- **Published health economic model demonstrating hospital cost savings**
- **\$2B + market opportunity**
 - Platform technology with numerous adjacent applications

INJURIES

- In-patient Burns
- Out-patient Burns
- Pediatric Scalds
- Soft Tissue Reconstruction
- Traumatic Wounds

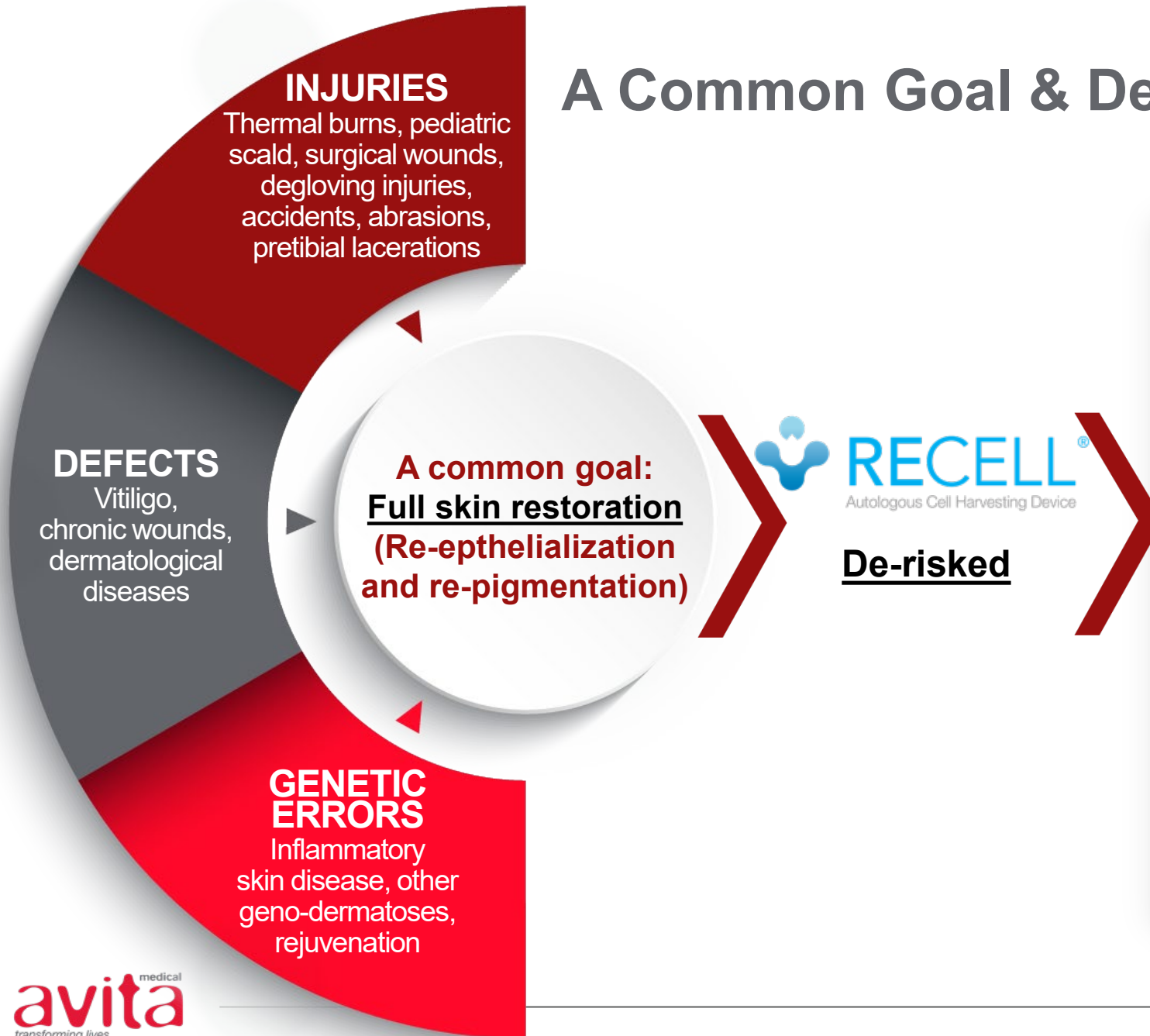
DEFECTS

- Vitiligo
- Chronic Wounds (DFU + VLU)
- Dermatological Diseases

GENETIC ERRORS

- University of Colorado Anschutz Medical Campus
 - Epidermolysis Bullosa
- New Sponsored Research
 - Rejuvenation

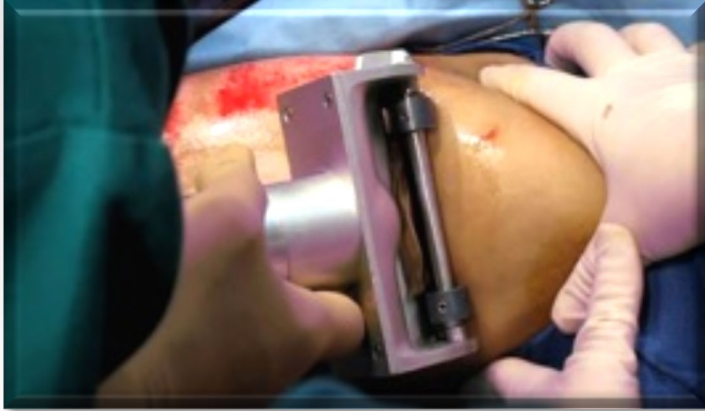
A Common Goal & Deep Clinical Experience



Patients (In studies)		Peer Reviewed Publications
858	Burns	75
1st PMA approved burn product in >20 years*		
77	Non-Healing Wounds (DFU, VLU)	6
120	Defects / Vitiligo	14
68	Acute Wounds (Non-Thermal)	9
>8,000 Patients Treated Globally		

Skin Grafting is Unchanged for More Than 50 Years

Split-Thickness Skin Grafts (STSG) are “Medieval”



Dermatome skin harvesting from new donor site



New (second) donor wound created via skin harvesting

KEY SHORTCOMINGS OF STSG

- **Large donor area** required
- **Pain** associated with donor site
- **Prolonged hospitalization + high costs**
- Multiple **complex, costly, surgical procedures**
- Risk of **infection**
- **Scarring**

STSG requires HCPs to create or “duplicate” the wound

Challenges with Split-Thickness Skin Graft Outcomes

Scarring, functional impairment, pigmentation, infection ...

Donor Site Scarring / Failure to Heal



Donor Site Infection Risk



Pigmentation and Discoloration



Scarring, Atrophy, Contracture

Normal skin restoration (re-epithelialize and re-pigmentation) is the ultimate goal

The RECELL Solution ... Spray-On Skin™



AUTOLOGOUS

Cell Harvesting Device that delivers Spray-On Skin™ Cells within 30 minutes at the point of care

ACTIVATED

Fresh (non-cultured cells) with the "free edge healing cascade"

DONOR SPARING

Treatment area = 80x donor area
(credit card size skin sample can treat an entire adult back)

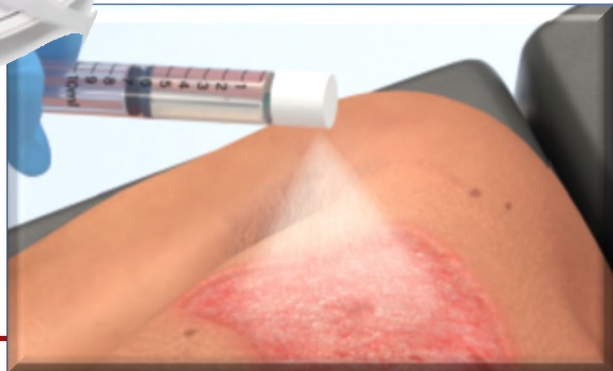
COMPLETE

Full range of skin cell types with re-pigmentation

SAFE & EFFECTIVE

2x PMA randomized controlled trials
1st PMA burn product approval ~ 20 yrs
8K+ clinical uses & 50+ publications

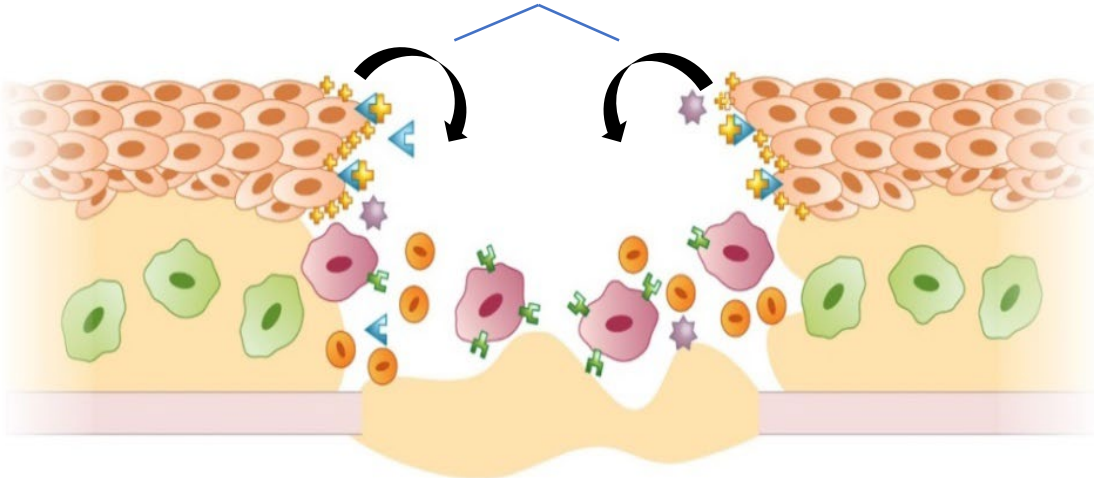
PUBLISHED HEALTH ECONOMIC DATA



RECELL's "Free Edge" Advantage

Healing Process without RECELL

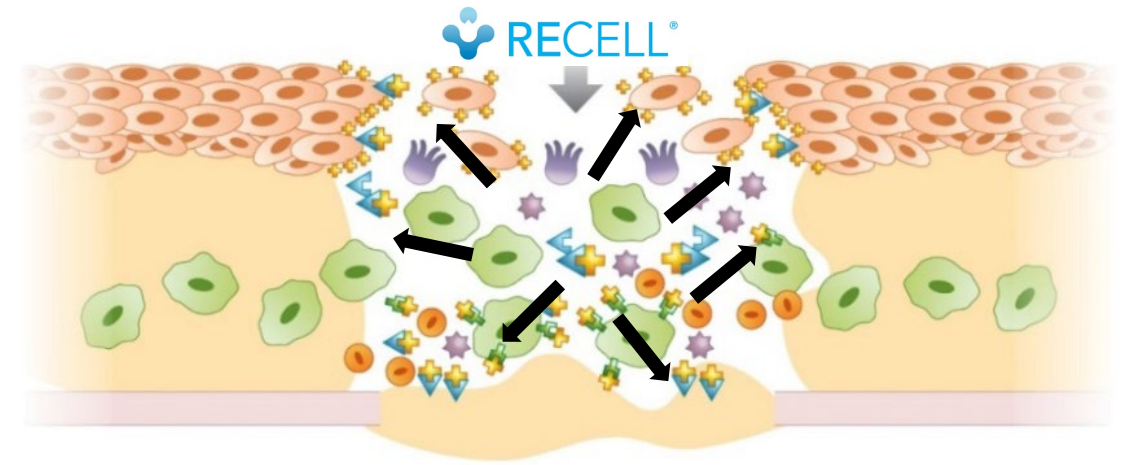
Free edge limits signaling to wound boundary (i.e. outside → in)



- The wound boundary acts as a "free edge" between injured and uninjured cells
- The absence of neighbor cells at the free edge triggers a healing signal which promotes cell proliferation and migration (myofibroblasts)
- New tissue growth is localized to the wound boundary (free edge)

Healing Process with RECELL

Spray-On Skin™ signals from within the wound (i.e. inside → out)



- RECELL uses the patient's skin to create a cell suspension of disaggregated (autologous) cells that are sprayed across the entire wound
- RECELL creates a broader free edge effect with more numerous signaling cells thus unleashing the free edge effect across the wound surface area
- New tissue proliferates across the entire surface area of the wound bed, now unrestricted to the free edges of the wound

RECELL Delivers Life-Changing Outcomes

Case Series Presented at 50th Annual ABA Meeting (2018)



Treatment Day



Day 7



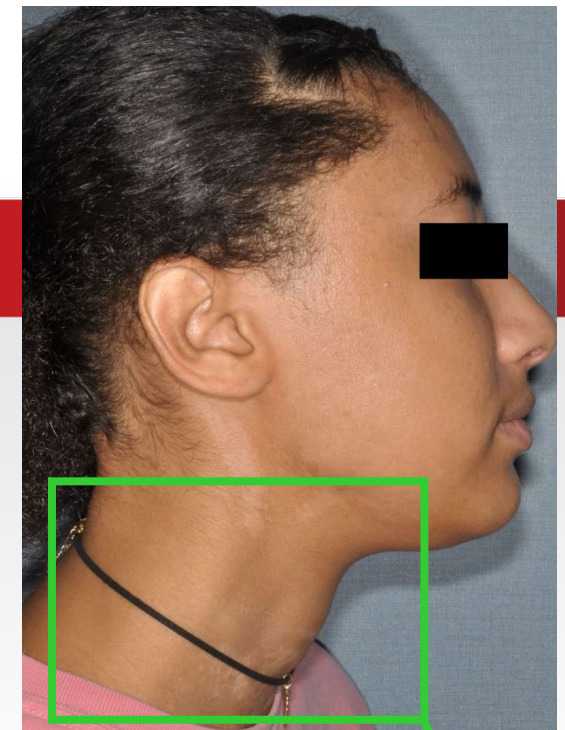
Day 21



3 Months



1 Year



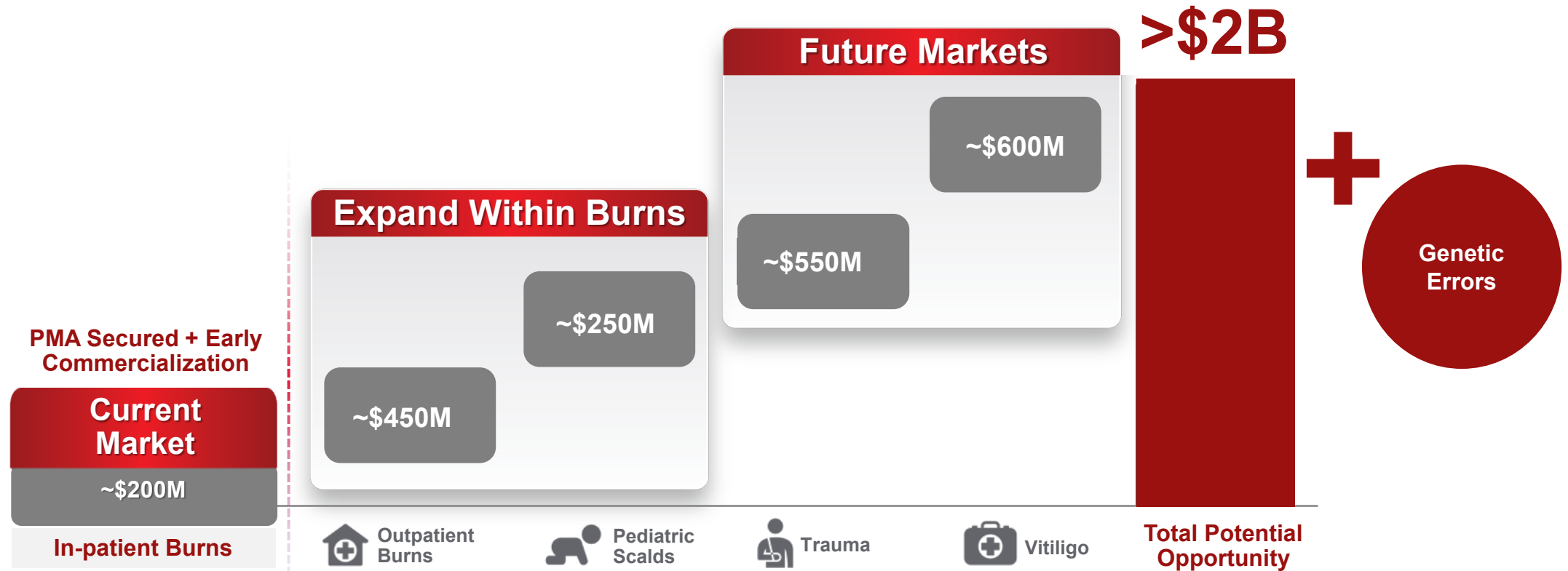
1 Year

- Compassionate Use case
- 12-year-old girl with 2nd-degree facial burn and widespread 3rd-degree burns
- 62% Total Body Surface Area (TBSA) burn injury
- Insufficient donor skin available for SoC (STSG)
- Reintroduction of melanocytes resulted in an excellent cosmetic outcome
- No facial contracture release surgery required
- Discharged in 24 days

Skin +
Color
Restoration

RECELL's treatment area is **80 times larger** than the donor site

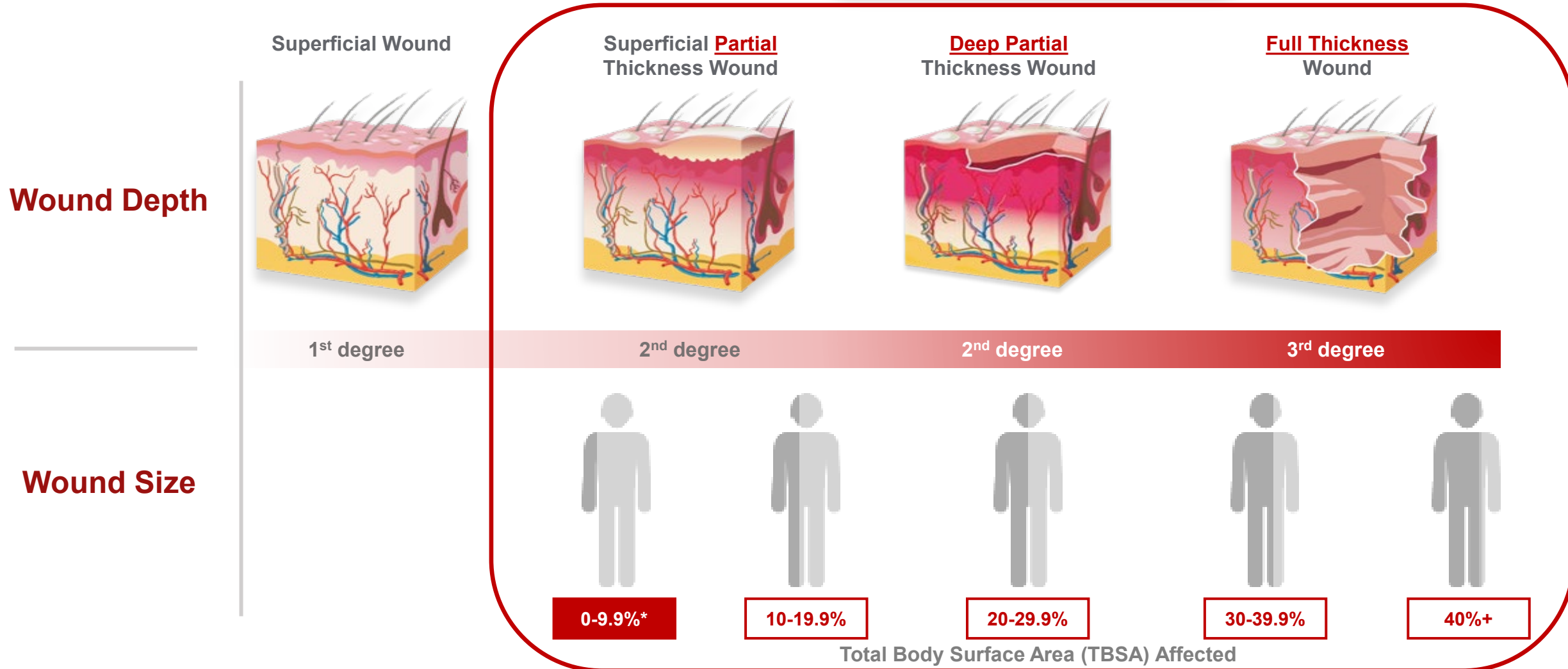
\$2 Billion Opportunity* and Existing U.S. Premarket Approval



* Estimates based on data on file at Avita Medical Limited

Burns Franchise

Burn Injury Framework



Burn Market Segmentation



~14,000
RECELL Eligible Patients

Current Burn Market
\$200M

In-patient Burns:
FDA PMA secured /
Commercializing



~110,000
2nd/3rd Degree
Adult Burn Injuries

Future Burn Markets
\$450M

Outpatient Burns:
Enhance Reimbursement
& Launch



~65,000
Pediatric Scalds Injuries

\$250M

Pediatric Scalds:
PMA Studies (2)
start in 2020



1st Premarket Approval Treatment in Burns in 20 Years

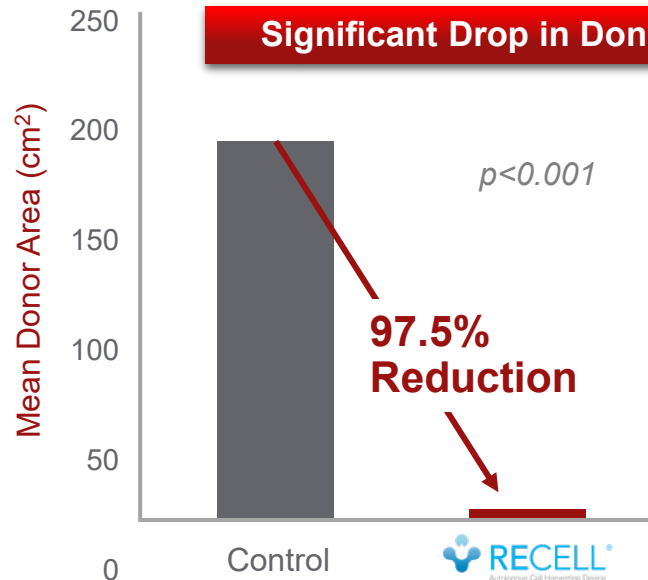
Dual multi-center, randomized, controlled premarket approval studies

Pivotal Trial #1 (101 Patients) RECELL (alone) versus SoC (STSG) in Second-Degree Burns

Published in JBCR and Presented at ABA



Significant Drop in Donor Skin Requirement



Decrease in donor site pain and scarring

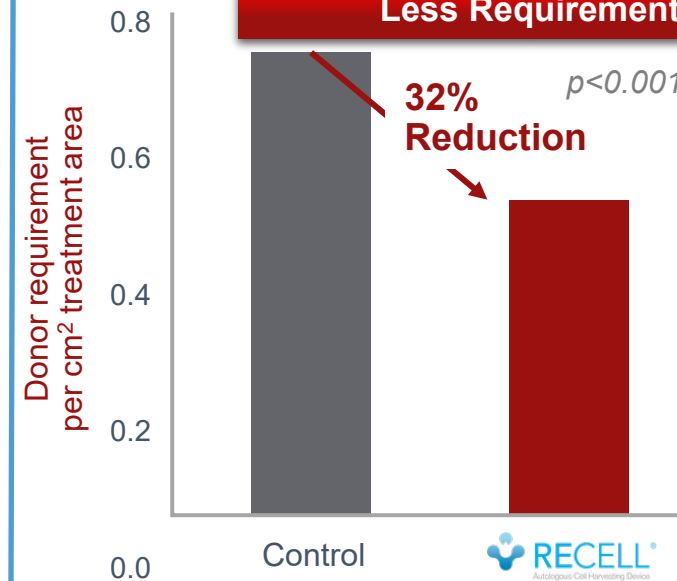
- Significantly less donor site pain ($p \leq 0.0025$)
- Significantly better donor site appearance ($p \leq 0.0025$)
- Significantly reduced donor site scarring ($p \leq 0.0025$)
- Significantly greater incidence of donor-site healing at two weeks ($p < 0.001$)

Pivotal Trial #2 (31 Patients) RECELL (with widely expanded graft) versus STSG in Third-Degree Burns

Published in Burns and Presented at ABA



Less Requirement for Donor Skin



Robust outcomes despite less donor skin

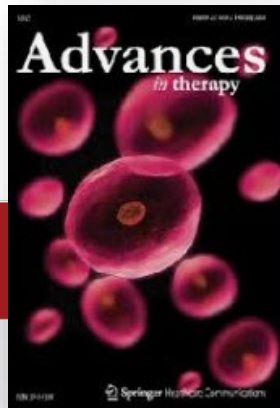
- RECELL System achieved definitive closure comparable to Standard of Care with significantly less donor skin
- At eight weeks post treatment, 92% of the burn sites treated with the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care

Comparable healing and long-term outcomes for burn sites with significantly less donor skin required

FDA Compassionate Use Investigational Device Exemption (IDE) Program (100 Patients)

FDA Continued Access Investigational Device Exemption (IDE) Program (88 Patients)

Published Health Economic Savings – Patient & Hospital Benefits

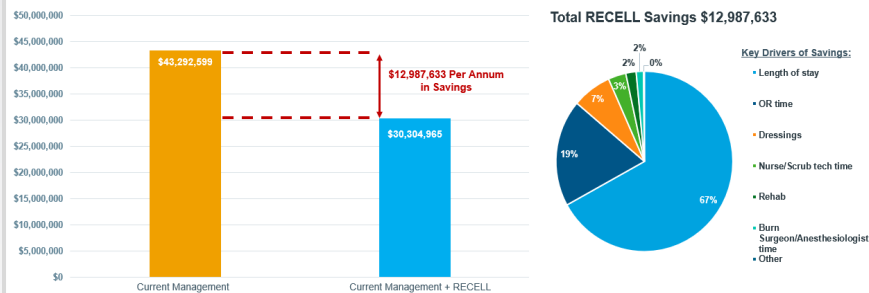


RECELL Reduces Overall Hospital Costs

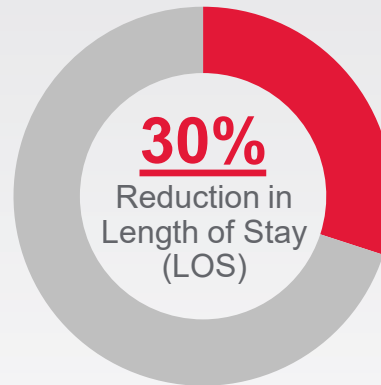
Transforming Care

Reduces costs and accelerates recovery by decreasing the number of painful procedures and length of stay in hospital

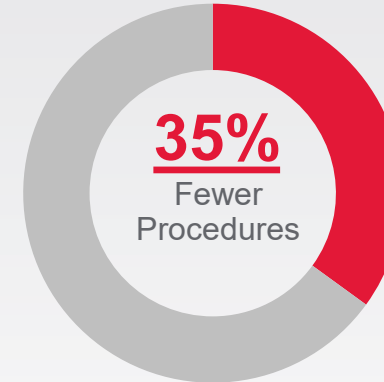
Annual budget impact of current management versus RECELL for a burn center with 200 patients



Conclusion: Considering the expected mix of patients entering a typical burn center each year (as informed by NBR data), use of RECELL is expected to reduce costs per treated patient and overall.



Fewer procedures and faster healing times get patients home more quickly



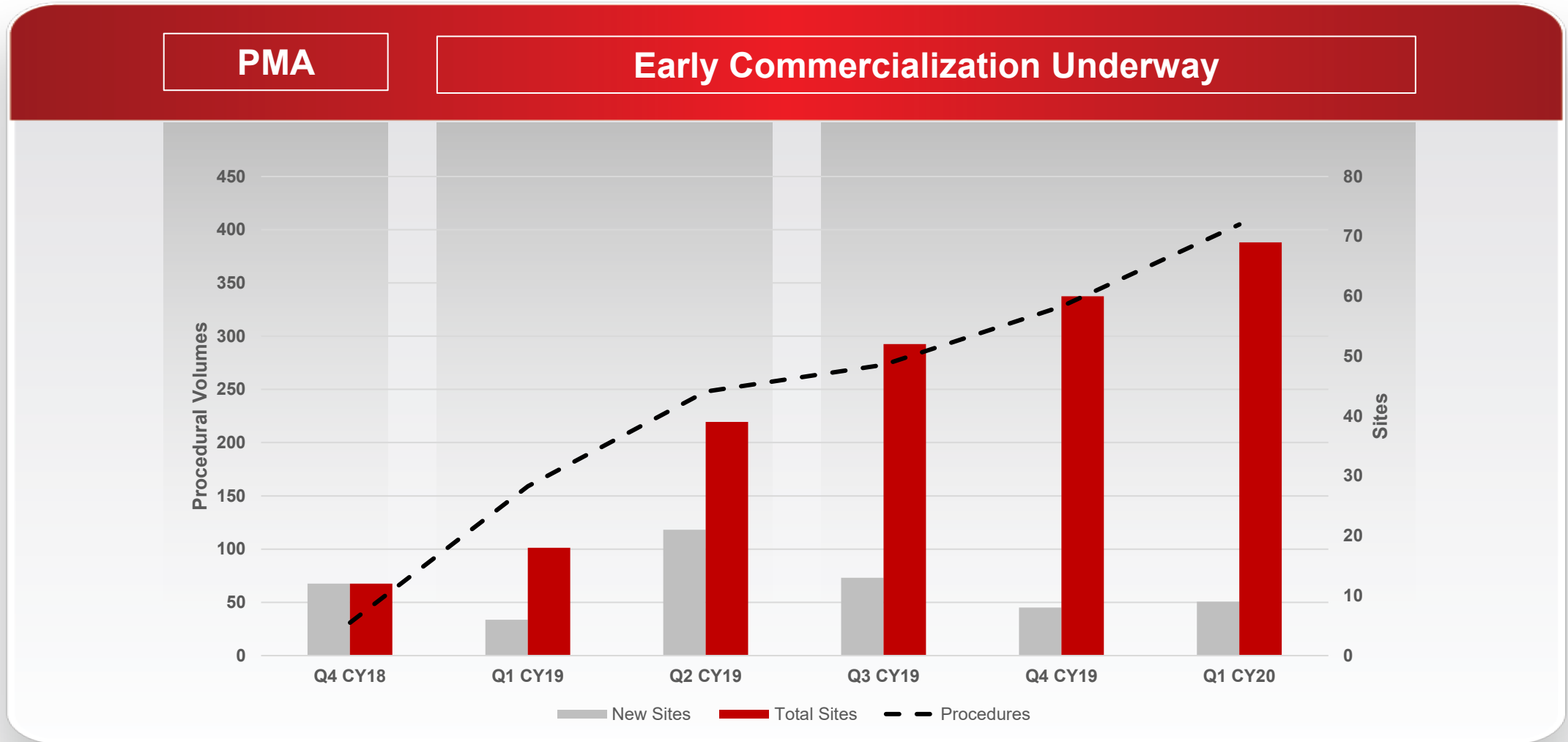
Reduced donor site size and greater meshing ratio enables permanent closure with fewer invasive autograft procedures



Shorter and fewer procedures, decreased length of stay, and reduced resource use translates into burn center savings

RECELL saves money in all in-patient scenarios where TBSA burn is > 10%

Strong Adoption of the RECELL System*



RECELL System procedural growth increasing quarter-on-quarter since PMA



Current Platform
~\$450M TAM

Second Target (Burn) Market

Out-patient burns

~430,000

outpatient burns

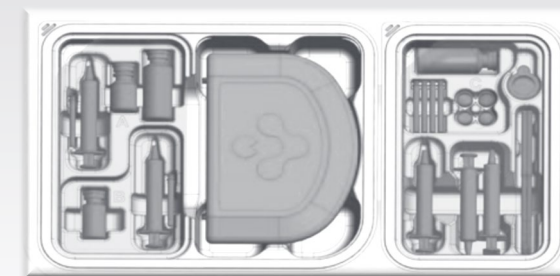
~37%

are 2nd and 3rd degree



Next Generation Device

focused on improved
efficiencies and ease
of use



Step 1: Pursue more favorable reimbursement

Step 2: RECELL “2.0” approval for market access

Targeting RECELL System launch in late H1 2021



Third Target (Burn) Market: Pediatric Patients

A unique subset

- **30%** of burns occur between 1 and 15 years of age **~45%** Estimated to be associated with scalds
- Scalds frequently present as “indeterminate depth” burns
- Skin defects healing > 3 weeks have a much higher rate of hypertrophic scarring
- Both painful donor sites and autografted areas can be disfiguring as the child grows

Case Study: 2-year old with scald treated with RECELL



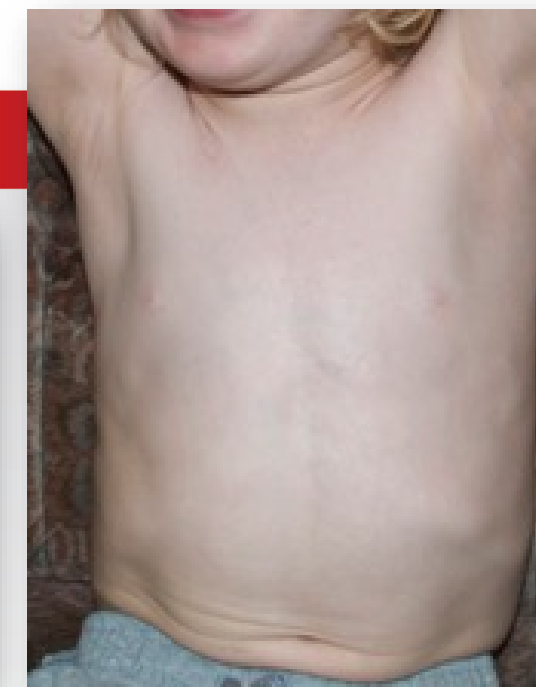
Before Treatment



*3 Weeks
post RECELL treatment*



*10 Weeks
post RECELL treatment*



*10 Months
post RECELL treatment*

Enrollment of U.S. pivotal studies to commence in mid-2020

Soft Tissue Reconstruction

Soft Tissue Grafting is 5 Times Larger Than Burns



Current Platform
~\$550M TAM



Road rash



Traumatic Wounds



Iatrogenic
(Surgically generated)



Skin cancer



Abrasions

Significant Unmet Need

Reduction of donor site morbidity and donor site requirements are top unmet needs

Strong Interest In RECELL

89% of respondents in surgeon research perceived the RECELL product profile as compelling

Synergistic with Current Commercial Efforts

70% of accounts currently purchasing RECELL also have trauma centers

Same Treatment Protocol to Burns

Consistent treatment protocol across acute injuries



Strong Success Indicators

RECELL used by multiple international surgeons in Traumatic Wounds with **positive outcomes**

Enrolling for U.S. pivotal study (N=65); First patient enrolled

Soft Tissue Reconstruction Closely Aligned to Burns



Current Platform
~\$550M TAM

Target Expands to ~250 Total Centers*

Current
AVITA Burn
Target:
~132
High Volume
Burn Dedicated
Centers*



Future
AVITA Trauma
Target:
~200
Level 1 Trauma
Centers*

> 1/2 of all U.S. burn centers are also Level 1 trauma centers

Defects

More Than 1,000 Vitiligo Patients Treated Internationally



Current Platform
~\$600M TAM

SIGNIFICANT UNMET NEED

Up to 2% of the population affected
(~6.5M in the US)*

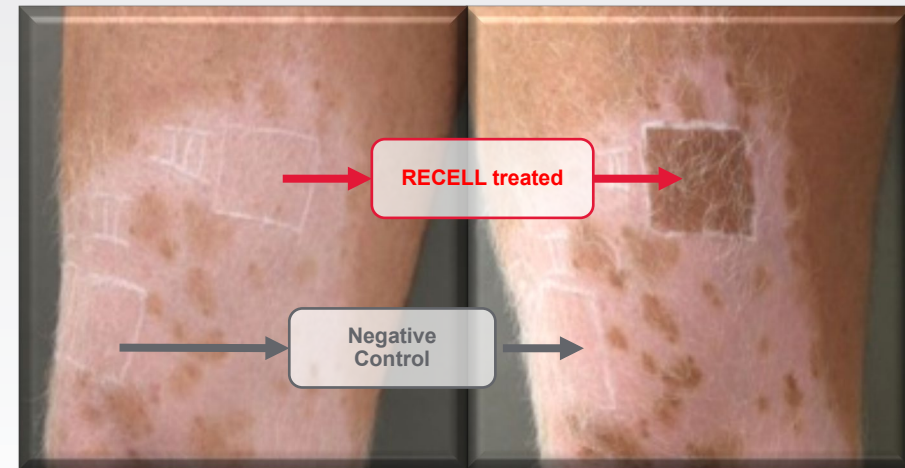
No FDA-approved medical treatments; extremely
low patient & physician
satisfaction with existing products

Vitiligo impacts quality of life (QoL)
- 25% had severe QoL reductions,
comparable to psoriasis

Growing reimbursement
(\$24,000 – \$42,000 / year for phototherapy)*

RECELL VALUE PROPOSITION

- Over 1,000 vitiligo patients treated internationally with RECELL
- 8 publications of RECELL in vitiligo with positive outcomes
- Potentially indicated for stable vitiligo of all types (segmental & non-segmental vitiligo)
 - JAK inhibitors could significantly increase the number of patients with stable disease



At 6 Months, RECELL-treated area was 100% re-pigmented

US feasibility study enrollment underway but exploring options for earlier pivotal study

Deep Experience in Chronic (Non-healing) Wounds

THE OPPORTUNITY

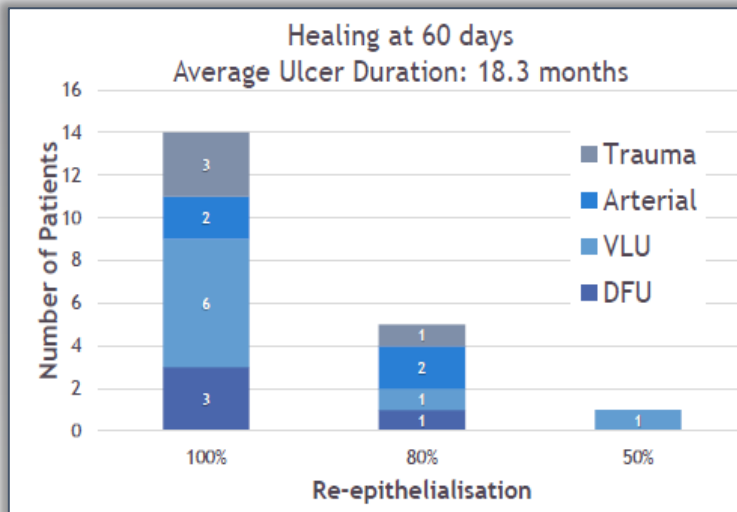
Chronic wounds fail to heal **50% of the time**

Failure to heal leads to pain, exudate (VLU), odor and infections

Dramatic Quality of Life impact
(e.g. activity restrictions, mobility, hygiene, sleep disorder)

RECELL VALUE PROPOSITION

- RECELL kick starts healing by providing healthy multi-phenotype single skin cells directly to the wound bed
- RECELL may provide faster & durable wound closure, reduced pain and positive QoL outcomes
- **Diabetic Foot Ulcer: 4 studies (2 RCTs) with 70 patients**
- **Venous Leg Ulcer: 4 studies (1 RCT) with 96 patients**



16 patients treated at three UK hospitals with chronic DFUs from 5-33 cm² were followed for 26 weeks.

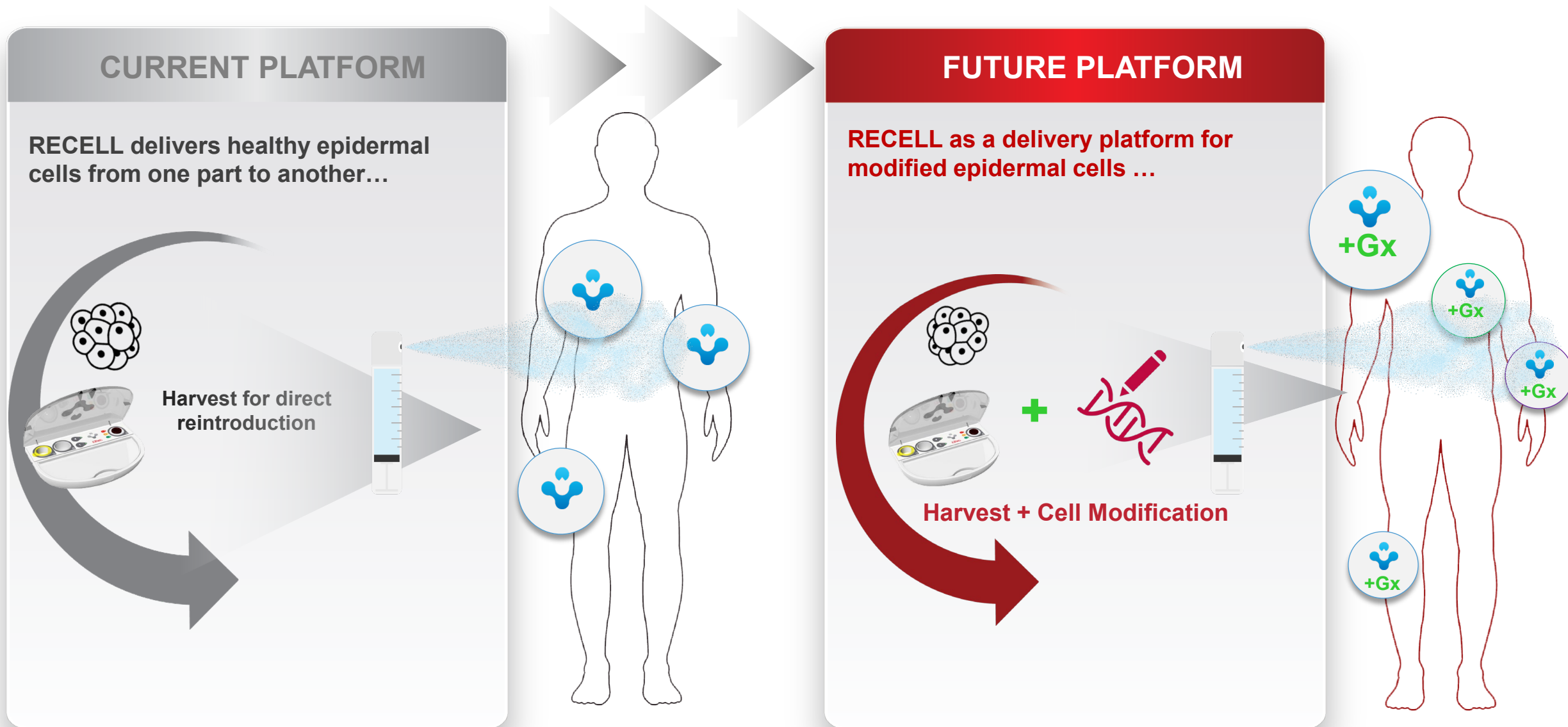
After RECELL:

- **100%** of patients experiencing a reduction in DFU wound size
- Average wound size **reduction - 83%** at week 26
- **50% of patients had DFU wounds heal completely**, with a median time to healing of 14 weeks

49% of all U.S. skin grafts are chronic wounds

Genetic Errors

RECELL in Genetic Skin Defects



* In the US, RECELL is approved for acute thermal burns in patients > 18 years ("ATB") only (see www.avitamedical.com). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.



Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa (EB)

The Challenge

Debilitating

Skin fragility, disability, cancer

High unmet need

No FDA-approved treatment

Rare

~3-8 per million in the US

Cost burden

Care of \$200k-\$500k/yr/patient*



The Opportunity

Curative

Correct underlying genetic defect

Efficient

Simplify manufacturing,
shorten time to treatment

Aesthetic

Scarless healing

Durable

Long-term wound closure

* Estimates and data based on information on file at Avita Medical Limited

Proof-of-concept in EB could open doors to other genetically correctable skin disorders

RECELL Well-Suited to Rejuvenation

Skin Rejuvenation*



- Americans spend **>\$16.5B** in aesthetic procedures annually
- **>3M** aesthetic procedures per year (US) aimed to improve skin tightness, texture & evenness in skin tone
- Consumers desire **superior results** over current offerings with a single treatment

* Estimates and data based on information on file at Avita Medical Limited

Avita is in late-stage discussions for a rejuvenation sponsored research agreement

Corporate

Impact of COVID-19 Pandemic

BURN BUSINESS

Non-Elective Procedure

- Patients suffering acute thermal burns require immediate treatment
- Burn procedures are not elective, and cannot be deferred
- Burn patients take up hospital beds, including ICU beds

Commercial Implications

- No material negative impact to revenue / procedural volumes through March 31st
- Difficult to assess longer-term impact of travel restrictions and social distancing
- New site ramp expected to slow given “movement restrictions”

OPERATIONS

Employees

- Implemented comprehensive work from home and social distancing policy
- Travel limited to essential travel
- Manufacturing continuing

Supply and Distribution

- No anticipated disruptions to supply chain or distribution network
- Sufficient raw materials to meet expected demand

Business “idling” and Well Capitalized

- Tightly focused on existing objectives and managing expenses

STUDIES & SUPPORT

Field Participation and Support

- Comprehensive digital and audio outreach program implemented
- Virtual case support and site training implemented
- Clinical onsite hospital support provided in a minority of territories but limited to urgent cases

Clinical Studies

- Investigational studies have been de-prioritized at all institutions
- Enrollment in all studies expected to be delayed

Adapting to Meet the Needs of Patients and Customers



Intellectual Property

ROBUST PROTECTION...

Cell Suspension Preparation Technique / Device

- Commercial RECELL device, composition of matter, and associated methods of use

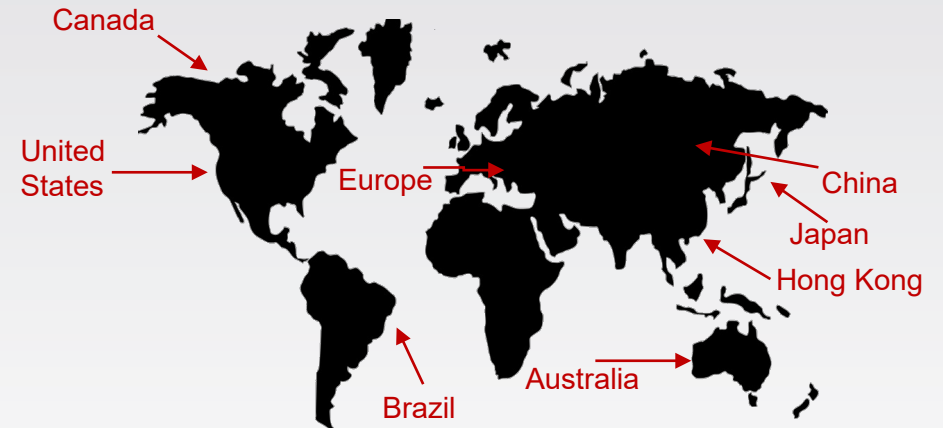
Cell Suspension And Use Thereof

- Method of preparing cell suspension with exogenous agent to promote wound healing

Method And Composition for Epithelial Regeneration

- Automated apparatus, next generation sprayer and method of production (pending)

...ACROSS GEOGRAPHIES



A global total of 26 issued patents,
10 pending patent applications

Patent and patent applications expiration from 2022 to 2034

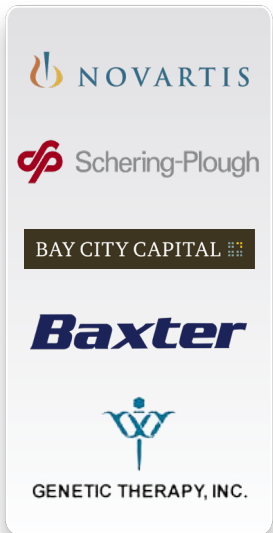
Experienced Leadership Team



Dr. Michael S. Perry
CEO

>30 years
experience

Affiliations:



David McIntyre
CFO

25 years
experience

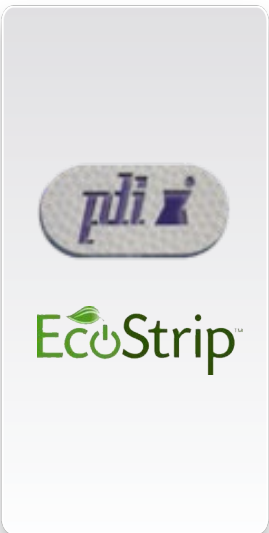
Affiliations:



Tim Rooney
CAO

25 years
experience

Affiliations:



Erin Liberto
CCO

17 years
experience

Affiliations:



Andrew Quick
CTO

25 years
experience

Affiliations:



Donna Shiroma
General Counsel

20 years
experience

Affiliations:



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- University of Colorado Anschutz Medical Campus
 - Epidermolysis Bullosa
- New Sponsored Research
 - Rejuvenation

Thank you

References

Sources of certain information included in this presentation are set out below for convenience.

Page 4: Kowal, S et al. Cost-effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States. Adv Ther. 2019; 36(7): 1715–1729.

Page 5: Images from <https://www.dailymail.co.uk/femail/article-3581558/Burns-survivor-bravely-bares-facial-scars-tells-emotional-story-driven-attempt-suicide-cruel-bullies-heart-wrenching-video.html>; <https://www.sciencedirect.com/topics/medicine-and-dentistry/burn-scar>;

Page 9: Kowal, S et al. Cost-effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States Adv Ther. 2019; 36(7): 1715–1729.

Page 10: Out-patient: 486,000 burns per year less 53,000 in-patient burns multiplied by adult factor of 70% multiplied by 37% factor to represent 2nd and 3rd degree burns (<http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>; Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013 HCUP/AHRQ, American Burn Association. National Burn Repository Report. 2016; Version 12.0 and internal market research). Scalds: 486,000 burns per year x 30% pediatrics factor x 45.2% scalds factor (American Burn Association. National Burn Repository Report. 2016); Version 12.0 also <http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>). Trauma: © 2017 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.; Vitiligo: American Academy of Dermatology- Vitiligo By the Numbers, 2017

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Page 14: Holmes JH, Molnar JA, Carter JE, et al. A comparative study of the RECELL® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. September/October 2018 issue (Volume 39, Issue 5); Holmes JH, Molnar JA, Shupp, JW, et al. Demonstration of the safety and effectiveness of the RECELL® System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. Burns. December 2018.

Page 15: Park JH, Heggie KM, Edgar DW, Bulsara MK, Wood FM. Does the type of skin replacement surgery influence the rate of infection in acute burn injured patients? Burns 2013;39:1386-90. <https://doi.org/10.1016/j.burns.2013.03.015>; Kowal, S., Kruger, E., Bilir, P. et al. Adv Ther (2019). <https://doi.org/10.1007/s12325-019-00961-2> ; Foster, K., et al. Cost-effectiveness of RECELL® Autologous Cell Harvesting Device (ACHD) Versus STSG for Treatment of Severe Burns in the United States. Presented at ABA, April 2018, Chicago, IL.

Page 18: American Burn Association NBR Advisory Committee, National Burn Repository 2016 Report, www.ameriburn.org/2016ABAFull.pdf; Chipp E, Charles L, Thomas C, Whiting K, Moiemmen N, Wilson Y. A prospective study of time of healing to healing of hypertrophic scarring in pediatric burns: everyday counts. Burns & Trauma 2017; 5:3. Published online 2017 Jan 19.

Page 21: 1. American Burn Association sources. In addition, see © 2017 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission -number of sites performing skin grafts for burn injuries.

Page 23: Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017; KOL input; internal market research 2018; Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009. Dermatology life Quality Index (DLQI) is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person; KOL input; internal market research 2018-2019; Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: A randomized controlled pilot study. Koman, et al. JAAD 2015.

Page 27: Prevalence estimate for DEB from ‘Epidemiology of Inherited Epidermolysis Bullosa Based on Incidence and Prevalence Estimates From the National Epidermolysis Bullosa Registry’; Fine J, JAMA Dermatol. 2016;152(11):1231-1238; Estimates based on dressing & other costs for adults and 10 year olds – ‘Management of chronic wounds in patients with dystrophic epidermolysis bullosa: challenges and solutions’, Rashidghamat and Mellerio, Chronic Wound Care Mgmt and Res, 2017, Vol :4 Pages 45—54; Genodermatoses & Rare Skin Disorders Network. Source of image: “A case of a patient with severe epidermolysis bullosa surviving to adulthood”, Hubail et al, International Journal of General Medicine, 2018, Volume 2018:11, Page 413

Page 29: [2017 Plastic Surgery Statistics Report](#)