UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 26, 2020

Avita Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39059**	**85-1021707**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

28159 Avenue Stanford, Suite 220, Valencia, CA 91355	**661.367.9170**
(Address of principal executive offices, including Zip Code)	**(Registrant's telephone number, including area code)**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**RCEL The Nasdaq**	**Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On August 26, 2020, Avita Therapeutics, Inc. (the "Company"), lodged the Company's update on corporate development activities with the Australian Securities Exchange. The aforementioned update included a copy of the Company's revised corporate presentation. A copy of the Company's update is attached hereto as Exhibit 99.1.

Additionally, on August 26, 2020, the Company issued a press release detailing identical information as the above-referenced Company update. A copy of the Company's press release is attached hereto as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Company Update and Revised Corporate Presentation
99.2	Press Release – Company Update and Revised Corporate Presentation

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 27, 2020

AVITA THERAPEUTICS, INC.

By: /s/ David McIntyre
Name: David McIntyre
Title: Chief Financial Officer

AVITA Therapeutics Provides Company Update and Revised Corporate Presentation

Valencia, Calif., USA, and Melbourne, Australia, August 26, 2020 — AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX:AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today provided an update on corporate developments.

- U.S. RECELL® System Sales:
  - July represented the highest monthly sales for RECELL Systems in the United States since launch in January 2019.
  - Unaudited sales for the RECELL System in July were U.S.$1.83 million.
  - July also witnessed very broad utilization of the RECELL System with 57 unique account orders, and more than 90 physicians using the RECELL System.
  - AVITA expects quarterly revenue in the September quarter to resume growth, and for sales to exceed the U.S.$3.9 million previously reported for the three (3) months ended June 30, 2020.
    - Recall that in the quarter ended June 30, 2020 revenue was deeply impacted by COVID in the United States with sales in the month of April down approximately 25% (versus the previous month).
    - Revenue then recovered in both May and June to deliver a flat sequential quarterly revenue result from the March quarter to the June quarter.
- Clinical Studies:
  - As previously advised, the U.S. Food & Drug Administration (FDA) granted an investigational device exemption (IDE) to support a vitiligo pivotal study on July 2nd, 2020.
  - Since receipt of the IDE, the Company has worked aggressively to obtain investigational review board approval (IRB) to support initiation of this study, together with commencing contracting discussions with potential clinical sites.
  - AVITA expects to treat our first vitiligo patient during September 2020.
  - There is a very high degree of both patient and clinical site enthusiasm in participating in our vitiligo pivotal study. Further, the Company continues to believe that the RECELL System is uniquely positioned to offer vitiligo patients a single curative therapy given that the RECELL System has been used to treat over 1,000 vitiligo patients internationally, and has been shown to provide patient benefits to vitiligo patients in eight (8) per-reviewed publications.
  - AVITA is also actively endeavoring to increase the number of clinical studies participating in each of our clinical studies. Additional clinical study sites have recently been added to both the pediatric scald and the soft tissue pivotal studies, and more sites are expected to be onboarded over the next few months.

- Corporate:
  - The Company expects to release its Annual Report for the twelve (12) months ended June 30, 2020 on August 28th.
  - The Company will participate both in the Morgan Stanley Virtual 18th Annual Global Healthcare Conference and the Cantor Global Healthcare Conference which are both scheduled to take place in September.
  - A copy of the Company's revised corporate presentation is available on the Company's website and is attached to this presentation.

For more detailed information on the Company's recent developments, please see our press release dated July 10, 2020 (which is available on both the Company's and ASX's website).

Authorized for release by the Chief Executive Officer of Avita Therapeutics, Inc.

# # #

ABOUT AVITA THERAPEUTICS, INC.

AVITA Therapeutics is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Therapeutics' patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RES® REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Therapeutics' first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is indicated for use in the treatment of acute thermal burns in patients 18 years and older. The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 8,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE—RECELL® Autologous Cell Harvesting Device (https://recellsystem.com/) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets, our products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL System is TGA-registered in Australia and received CE-mark approval in Europe.

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe,"

“estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “continue,” “outlook,” “guidance,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward- looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company’s control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

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PR20200826

AVITA Therapeutics

Dr. Mike Perry, CEO

August 2020

Disclaimer

This presentation is made available by AVITA Therapeutics, Inc. ("AVITA", "the Company", or "we"). It is intended to provide background information only, and may not be reproduced or redistributed in whole or in part nor may its contents be disclosed to any other person.

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. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks and uncertainties. The future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. This presentation also includes clinical, financial, market and related industry statements which are based on publicly-available information, or from data held on file at the Company.

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 Therapeutics: Spray-On Skin™

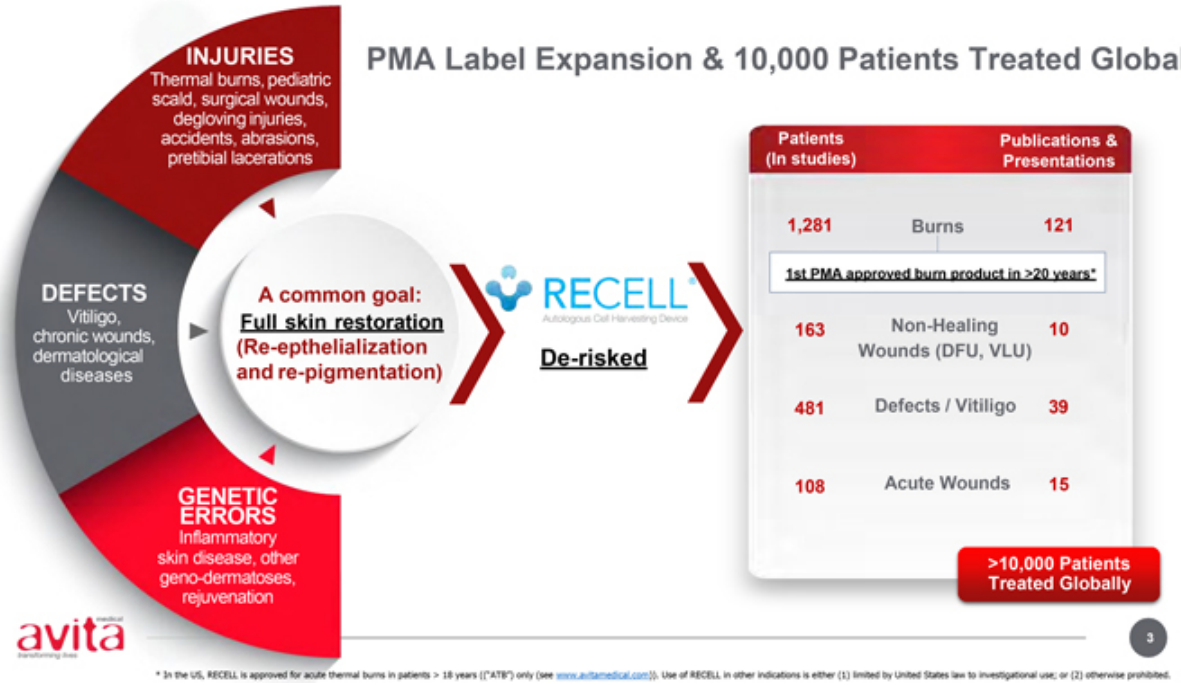
Spray-On Skin Enables Skin Regeneration

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 randomized controlled trials + and 1st PMA in burns in >20yrs**
  - 10,000+ patients, 180+ publications and presentations
  - U.S. FDA approved for acute burns*
- **Published health economic model demonstrating hospital cost savings**
- **Multi-billion serviceable market opportunity**
  - Platform technology with numerous adjacent applications
- **PMA label expansion underway with three (3) pivotal studies**

* 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.

PMA Label Expansion & 10,000 Patients Treated Globally



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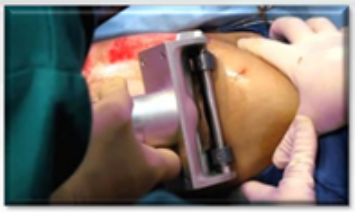
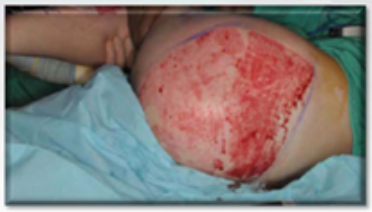
Treating "Skin Injury" is Unchanged for More Than 50 Years

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

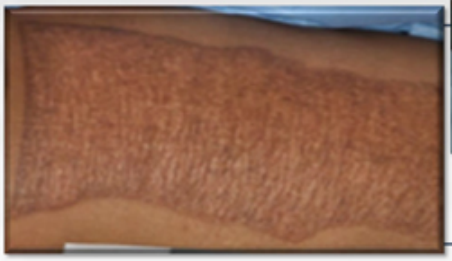
- **Large donor area** required
- **Pain** associated with donor site
- **Prolonged hospitalization + high costs**
- Multiple **complex, costly, surgical procedures**
- Risk of **infection**
- **Scarring**

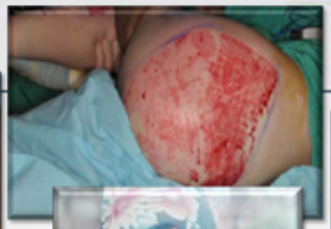
STSG is the Standard of Care and requires physicians to create a new (donor) wound

Challenges with Split-Thickness Skin Graft Outcomes

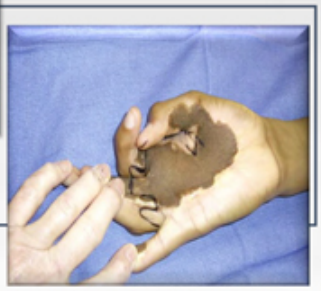
Scarring, functional impairment, pigmentation, infection …

Donor Site Scarring / Failure to Heal





Donor Site Infection Risk



Pigmentation and Discoloration

Scarring, Atrophy, Contracture

Scarring, re-operations, excessive pain, infection, contracture …

RECELL Spray-On Skin™ Treats 80cm² of Skin from a 1cm² Biopsy

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
10K+ clinical uses & 150+ reviews

PUBLISHED HEALTH ECONOMIC DATA

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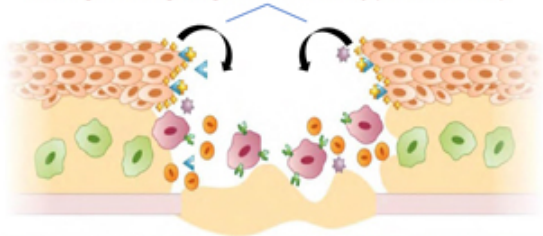
RECELL's "Free Edge" Advantage

Healing Process without RECELL

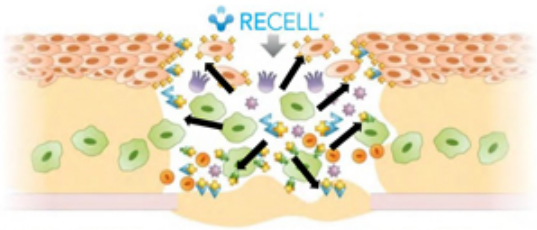
Free edge limits signaling to wound boundary (i.e. outside → in)



- 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

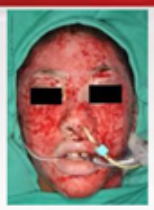
Spray-On Skin™ signals from within the wound (i.e. inside → out)

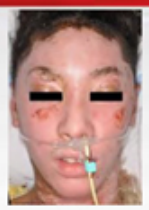


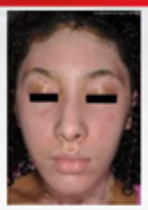
- RECELL uses the patient's skin to create a cell suspension of disaggregated (autologous) cells that are sprayed across the entire wound
- RECELL creates a broader free edge effect with more numerous signaling cells thus unleashing the free edge effect across the wound surface area
- New tissue proliferates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

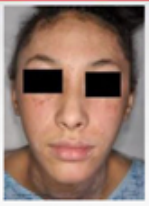
RECELL Delivers Life-Changing Outcomes

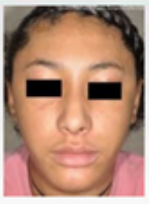
Case Series Presented at 50th Annual ABA Meeting (2018)


Treatment Day


Day 7


Day 21


3 Months


1 Year


1 Year

Skin + Color Restoration

- 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 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

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

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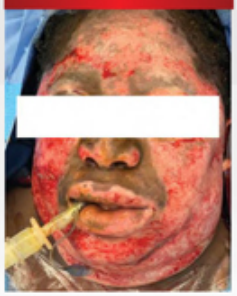
* In the US, RECELL is approved for acute thermal burns in patients > 18 years ("ATB") only (see www.avitamedical.com). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

Flexible Treatment Offering – Small Burns & Pigmentation

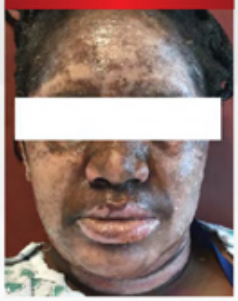
31-year-old female | 11% TBSA | DPT Face | RECELL® alone

Treatment Day



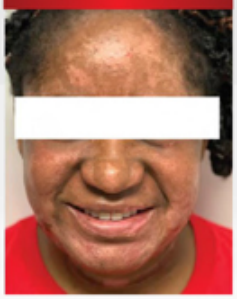
After 7 days of no progressive healing with allograft, Spray-On Skin™ Cells were applied

9 Days



Day 11, patient was discharged with 100% re-epithelialization and no signs of infection or inflammation

2 Months



2 months post-op, patient continued to show re-pigmentation

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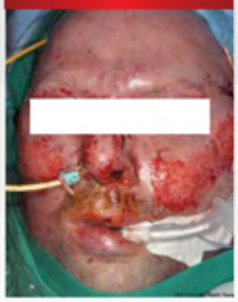
TBSA: total body surface area; DPT: deep-partial thickness burn

Promote Healing in Challenging Areas

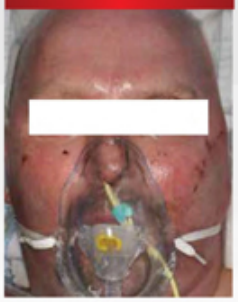
40-year-old male | <10% BSA | DPT Face | RECELL® alone

Treatment Day



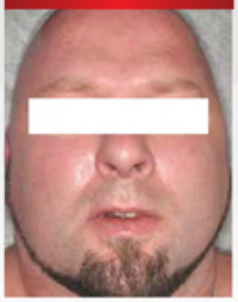
After 24 days of no progressive healing with allograft, Spray-On Skin™ Cells were applied

1 Week



At 1 week, 95% re-epithelialization occurred

5 Months



At 5 months, minimal scarring and consistent pigmentation were seen despite an anatomically challenging area

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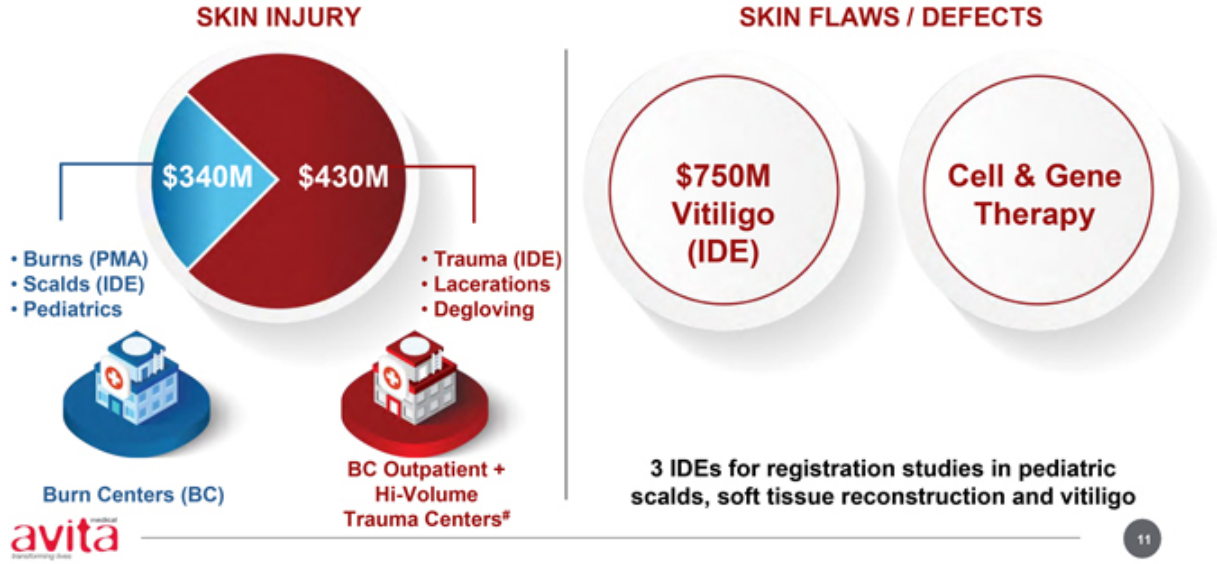
BSA: body surface area

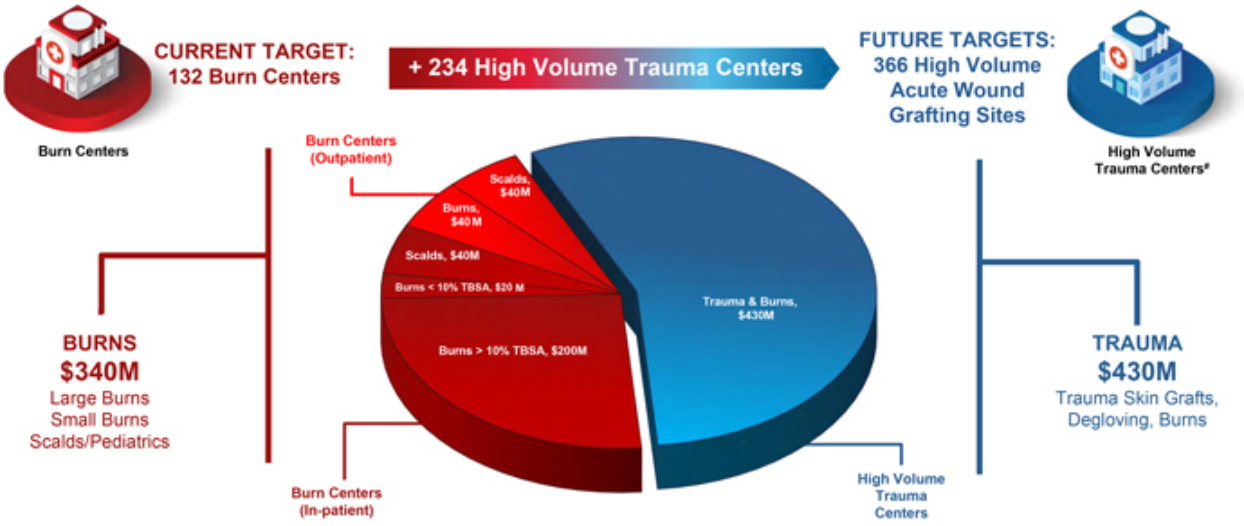
Leveraging Premarket Approval* in a Multi-Billion Serviceable Market



Decile 6+ trauma grafting sites; * 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.

Skin Injury

Skin Injury: Significant Opportunity + Concentrated Target



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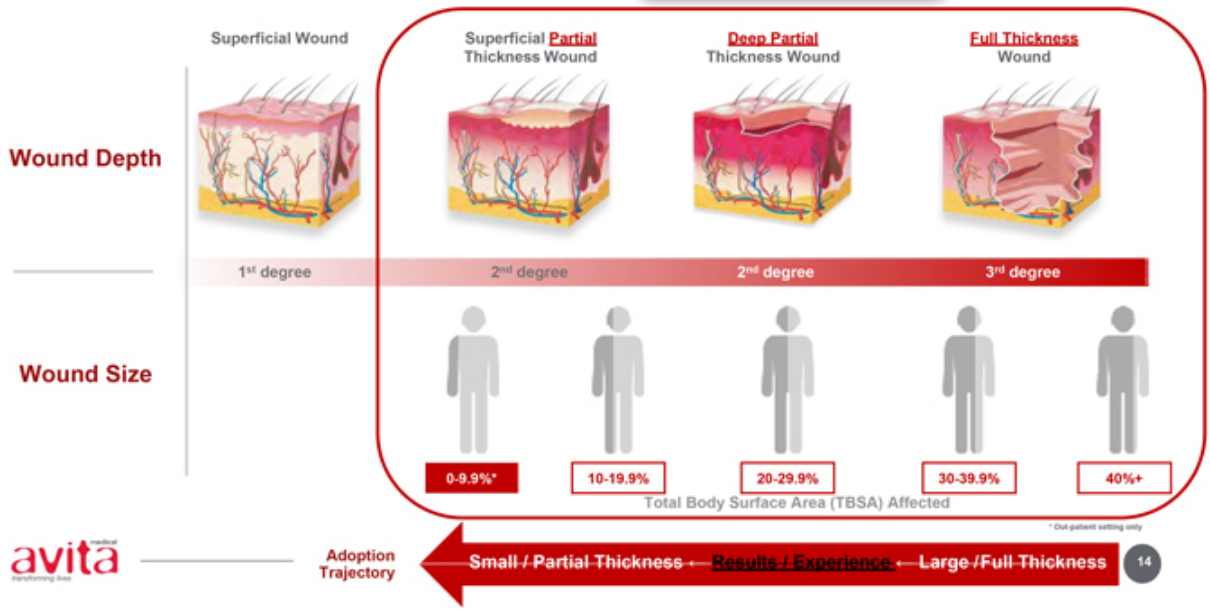
Opportunity concentrated at 366 High Volume Acute Wound Grafting Sites

Decile 6+ trauma grafting sites; * 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.

Skin Injury Framework

RECELL® TARGET



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Adoption Trajectory

~~Small / Partial Thickness~~ ← Results / Experience ← ~~Large / Full Thickness~~

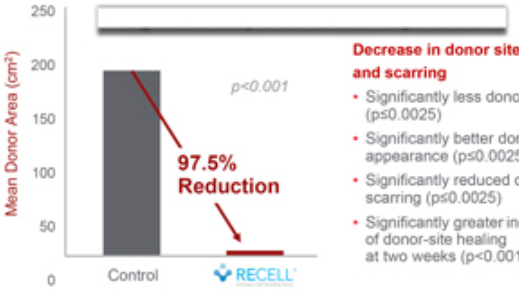
1st Premarket Approval Treatment in Burns in 20 Years

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



Decrease in donor site pain and scarring

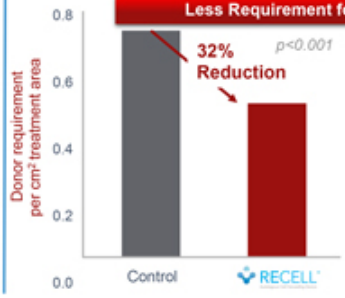
- Significantly less donor site pain (p≤0.0025)
- Significantly better donor site appearance (p≤0.0025)
- Significantly reduced donor site scarring (p≤0.0025)
- Significantly greater incidence of donor-site healing at two weeks (p<0.001)

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)

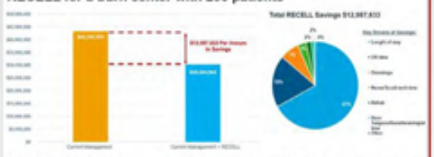
Published Health Economic Savings – Patient & Hospital Benefits

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%

Soft Tissue Grafting is 5 Times Larger Than Burns

- 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

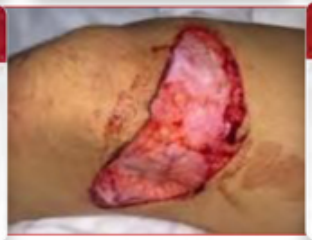
89% of respondents in surgeon research perceived the RECELL product profile as compelling

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

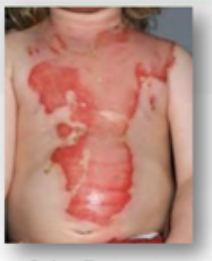
* In the US, RECELL is approved for acute thermal burns in patients > 18 years (see www.avitamedical.com). RECELL is an investigational device for soft tissue reconstruction ("STR") and is limited by United States law to investigational use in

Pediatric Patients

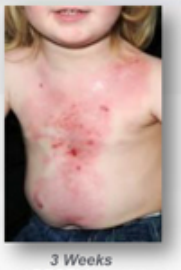
A unique subset

- **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

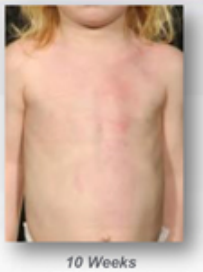
Case Study: 2-year old with scald treated with RECELL



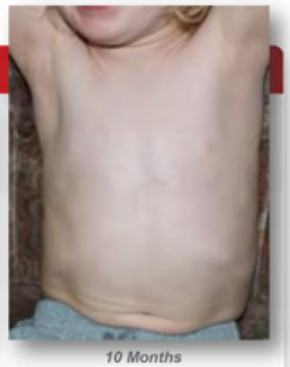
Before Treatment



3 Weeks post RECELL treatment



10 Weeks post RECELL treatment



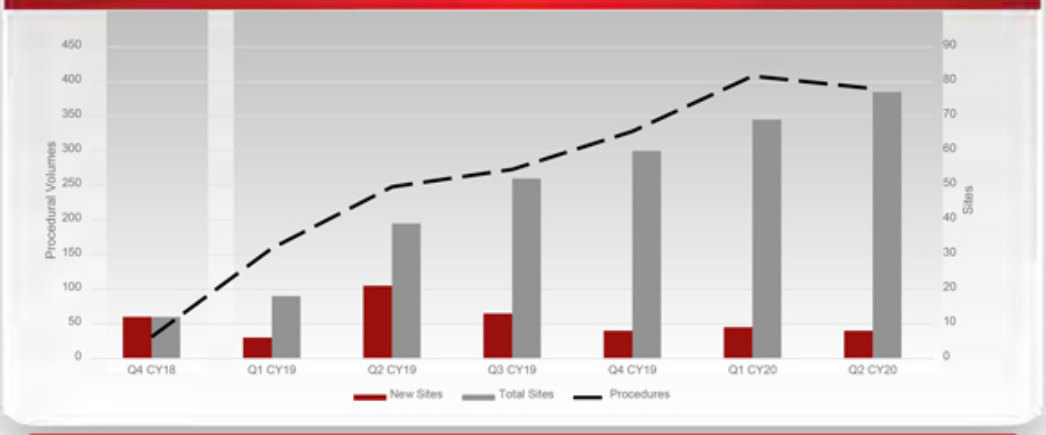
10 Months post RECELL treatment

First patient enrolled in U.S. pivotal studies

* In the United States, RECELL is not approved for pediatric use and is an investigational device, limited by United States law to investigational use for those patients

Strong Adoption of the RECELL System*

PMA | **Early Commercialization Underway**



RECELL System procedural growth since PMA

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Skin Flaws / Defects

1,000 Vitiligo Patients & 8 Peer-Reviewed Publications Showing Benefits

SIGNIFICANT UNMET NEED

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

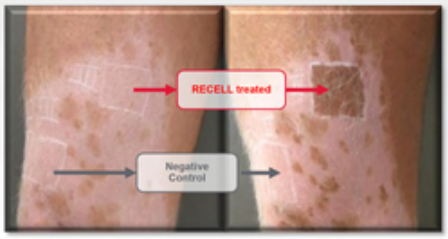
No FDA-approved medical treatments; extremely low patient & physician satisfaction with existing products

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

IDE granted for U.S. Pivotal Study; target first patient in 2H CY 2020

avita

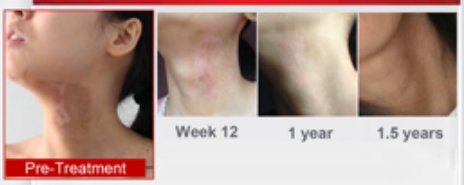
* Estimates and data based on information on file at AVITA Therapeutics, Inc.

* In the United States, RECELL is not approved for use with patients suffering vitiligo and is an investigational device, limited by United States law to investigational use for those patients

Significant Opportunity for a Single, Curative Therapy

FIRST LINE	SECOND LINE	THIRD LINE
Medical Management With Topicals* (Corticosteroids, Calcineurin inhibitors) • 2 treatments per week for 3-6 months • Limited efficacy (**45% regain some color**) • Poor patient compliance • Potential skin atrophy • Potential cancer risk	**Phototherapy and Laser*** (photobooth, excimer laser) • 2 to 3 treatments / week for several months sometimes exceeding a year • Typically in combination with topical • Efficacy reported up to 70% but not durable 	**Third Line Surgical therapies** (skin grafting, suction blistering, Melanocyte-Keratinocyte Transplantation (MKTP)) **Combination PUVA** (psoralen with light therapy) **Depigmentation of remaining color**

100% Re-pigmentation Observed



- 26-year-old woman with vitiligo vulgaris for 6 years, mainly around the neck
- Patient had received vitamins, steroids and medium-wave ultraviolet (UVB) irradiation treatment, all of which had no significant impact
- After diagnosis of stable vitiligo vulgaris, a patch on the neck (~10 cm2) was prepared with dermabrasion to pinpoint bleeding and treated with RECELL once

Zeng Ang, Liu Zhifei, Wang Xiaojun, Zhu Lin, Jia Yihong, Long Fei, and Sloubin, Clinical efficacy of ReCell® technology in the treatment of stable vitiligo [J]. Chinese Journal of Medical Aesthetics, 2014, 20 (6): 444-446

Meaningful Experience in Chronic (Non-healing) Wounds

THE OPPORTUNITY

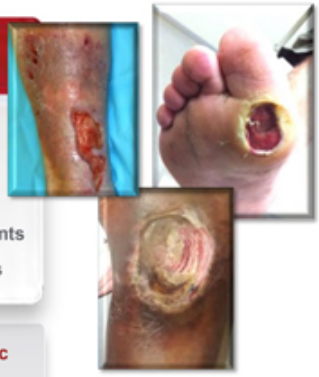
Chronic wounds (e.g. VLUs) fail to heal 50% of the time

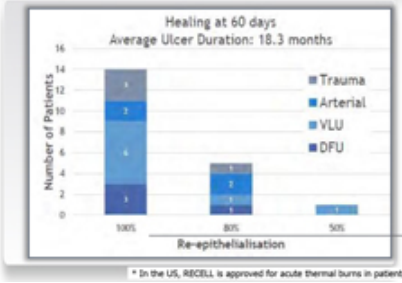
Failure to heal leads to pain, exudate (VLU), odor and infections

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

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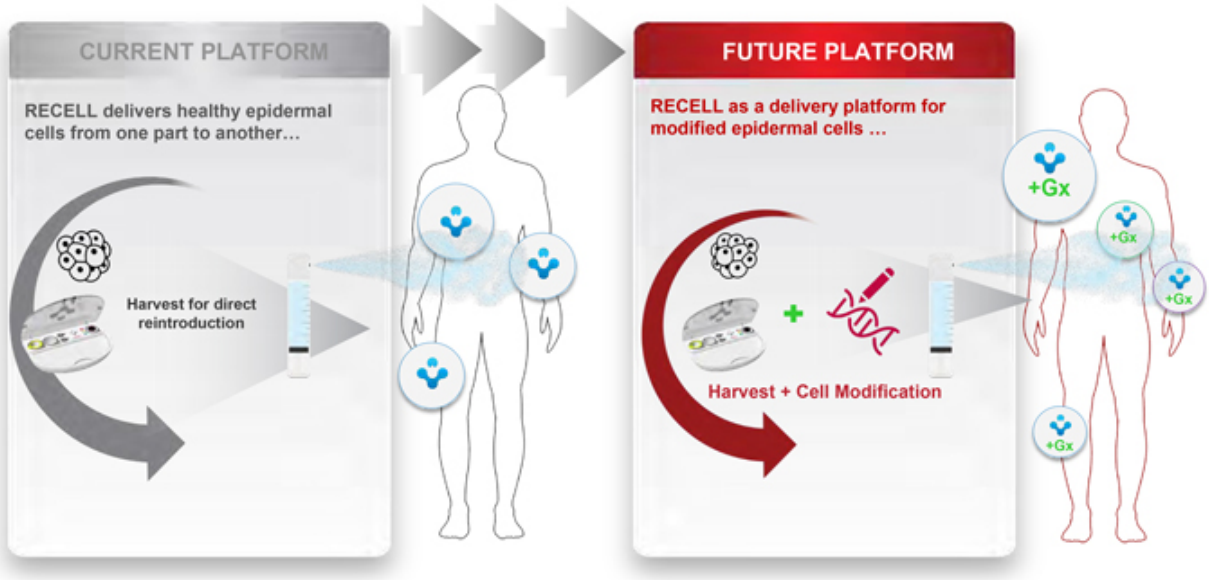
Cell / Gene Therapy

RECELL in Genetic Skin Defects



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

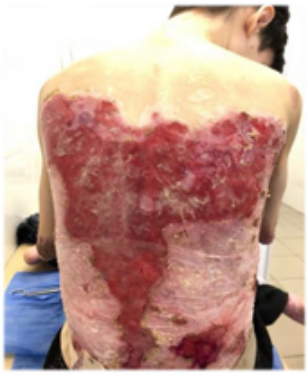
The Challenge

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 Therapeutics, Inc.

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

avita medical

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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

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Corporate

COVID-19 Pandemic Update

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

- April negatively impacted, but May /June "corrected" – hoping to resume growth
- Procedural volumes vary regionally depending on local COVID dynamics
- New site ramp may be slower given movement and site access restrictions

OPERATIONS

Employees

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

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 highly restricted, and often solely at "physician request"

Clinical Studies

- Investigational studies have been de-prioritized at all institutions
- Enrollment in all studies slow, especially in the emergency setting (where COVID capacity is needed)

Safety and welfare of employees, patients, HCPs and stakeholders are paramount

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 (2024 with Hatch-Waxman) to 2034

Note: Patents in Canada and China are pending. Other geographies have at least one granted patent. European countries covered by at least one patent include – Austria, Belgium, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, Turkey, United Kingdom.

Experienced Leadership Team

Dr. Michael S. Perry
CEO

>30 years experience

Affiliations:

NOVARTIS
Schering-Plough
BAY CITY CAPITAL
Baxter
GENETIC THERAPY, INC.

David McIntyre
CFO

25 years experience

Affiliations:

HeartWare
A T P
Baker McKenzie.
KPMG

Erin Liberto
CCO

17 years experience

Affiliations:

Johnson & Johnson
Allergan

Andrew Quick
CTO

25 years experience

Affiliations:

Boston Scientific
AB
sonova

Donna Shiroma
General Counsel

20 years experience

Affiliations:

ASCEND THERAPEUTICS
PDL BioPharma
Johnson & Johnson

avita medical

AVITA Therapeutics: Spray-On Skin™

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 randomized controlled trials + and 1st PMA in burns in >20yrs**
  - 10,000+ patients, 180+ publications and presentations
  - U.S. FDA approved for acute burns*
- **Published health economic model demonstrating hospital cost savings**
- **Multi-billion serviceable market opportunity**
  - Platform technology with numerous adjacent applications
- **PMA label expansion underway with three (3) pivotal studies**

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AVITA Therapeutics Provides Company Update and Revised Corporate Presentation

August 26, 2020

VALENCIA, Calif. & MELBOURNE, Australia—(BUSINESS WIRE)— Aug. 26, 2020— AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX: AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today provided an update on corporate developments.

- U.S. RECELL® System Sales:
  - July represented the highest monthly sales for RECELL Systems in the United States since launch in January 2019.
  - Unaudited sales for the RECELL System in July were U.S.$1.83 million.
  - July also witnessed very broad utilization of the RECELL System with 57 unique account orders, and more than 90 physicians using the RECELL System.
  - AVITA expects quarterly revenue in the September quarter to resume growth, and for sales to exceed the U.S.$3.9 million previously reported for the three (3) months ended June 30, 2020.
    - Recall that in the quarter ended June 30, 2020 revenue was deeply impacted by COVID in the United States with sales in the month of April down approximately 25% (versus the previous month).
    - Revenue then recovered in both May and June to deliver a flat sequential quarterly revenue result from the March quarter to the June quarter.
- Clinical Studies:
  - As previously advised, the U.S. Food & Drug Administration (FDA) granted an investigational device exemption (IDE) to support a vitiligo pivotal study on July 2nd, 2020.
  - Since receipt of the IDE, the Company has worked aggressively to obtain investigational review board approval (IRB) to support initiation of this study, together with commencing contracting discussions with potential clinical sites.
  - AVITA expects to treat our first vitiligo patient during September 2020.
  - There is a very high degree of both patient and clinical site enthusiasm in participating in our vitiligo pivotal study. Further, the Company continues to believe that the RECELL System is uniquely positioned to offer vitiligo patients a single curative therapy given that the RECELL System has been used to treat over 1,000 vitiligo patients internationally, and has been shown to provide patient benefits to vitiligo patients in eight (8) peer-reviewed publications.
  - AVITA is also actively endeavoring to increase the number of clinical studies participating in each of our clinical studies. Additional clinical study sites have recently been added to both the pediatric scald and the soft tissue pivotal studies, and more sites are expected to be onboarded over the next few months.
- Corporate:
  - The Company expects to release its Annual Report for the twelve (12) months ended June 30, 2020 on August 28th.
  - The Company will participate both in the Morgan Stanley Virtual 18th Annual Global Healthcare Conference and the Cantor Global Healthcare Conference, which are both scheduled to take place in September.
  - A copy of the Company's revised corporate presentation is available on the Company's website.

For more detailed information on the Company's recent developments, please see our press release dated July 10, 2020 (which is available on both the Company's and ASX's website).

Authorized for release by the Chief Executive Officer of AVITA Therapeutics, Inc.

ABOUT AVITA THERAPEUTICS, INC.

AVITA Therapeutics is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Therapeutics' patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RES ® REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Therapeutics' first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is indicated for use in the treatment of acute thermal burns in patients 18 years and older. The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing

the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 8,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE—RECELL® Autologous Cell Harvesting Device (https://recellsystem.com/) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets, our products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL System is TGA-registered in Australia and received CE-mark approval in Europe.

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

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