
avita medical
Annual General Meeting

21 November 2014



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CEO Address Outline

- **Where we are today**
 - Clarity and unity across Board and Management
 - On track with commercialisation strategy
- **Progress since 2013 AGM**
 - Established unique selling propositions (USPs) in focused clinical indications
 - A leader amongst peers in regenerative cell-based therapeutics
- **Well positioned for growth**
 - Refined commercial strategy and clarity with FDA around key US burns trial development timeline
 - Regenerative medicine is becoming a “hot” space
- **A look forward**
 - Upcoming milestones in proving out commercial models for successful partnering



Where we are Today

- **Leadership aligned and poised to facilitate our transition to next stage of growth**
 - Shareholder concerns acknowledged and acted upon
 - Board/management issues from 2013 resolved
 - Team united and energized
- **Platform regenerative technology**
 - Implementing regenerative medicine focus around USPs within Acute Wounds (burns/trauma), Chronic Wounds (lower limb ulcers) and Aesthetics (e.g. repigmentation)
 - Key marketing, sales, product development and clinical achievements in each area this past year
- **Commercial stage (regenerative)**
 - Approved for marketing and generating revenues in key international territories across Europe, China and Australia
 - Vetting commercial models in preparation for strategic partnering
- **Respiratory product line provides additional, promising assets to leverage and/or grow**
 - Breath-A-Tech: Inhaled medication spacer for adults and children marketed in Australia
 - Funhaler: Inhaled medication incentive-spacer for children



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Regenerative Platform Technology Serves as Catalyst

Autologous Cell Harvesting Devices (single-use)

- Rapid (30 min) creation of a regenerative suspension, comprised of the patient's own skin cells and associated signaling factors, in an easy-to-use bedside kit for the clinician
- Delivers a suspension that harnesses the body's intrinsic capacity for self-repair
- Uniquely supports medical management of skin defects across a range of clinical areas
 - Repairing acute wounds, minimizing donor skin harvesting
 - Restarting healing in lower limb ulcers
 - Restoring natural pigment for aesthetic indications
- Addresses needs of all stakeholders:
 - **Patients:** Provides improved outcomes and quality-of-life;
 - **Surgeon/Clinician:** Easy, fast and effective with reduced morbidity; revenue generator; and
 - **Healthcare System:** Reduced patient care costs



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Intellectual Property

Avita Medical's regenerative technology platform is protected by a family of patents, granted (expiring 2022) and pending().*

Claim s	Area	Claim s	Area
Method, composition & apparatus	Australia	Method*	US
	Japan		US
	Brazil*	Composition*	US
Method & composition	Austria		US
	Belgium	Apparatus*	Europe
	France		Japan
	Germany	Augmented epithelial suspension method & composition*	PCT
	Great Britain		Australia
	Italy		Brazil
	Netherlands		Canada
	Portugal		China
	Sweden		Europe
	Turkey		Hong Kong
	Spain		Japan
	Hong Kong		US
		Automation for epithelial suspension apparatus & method*	PCT
			Australia



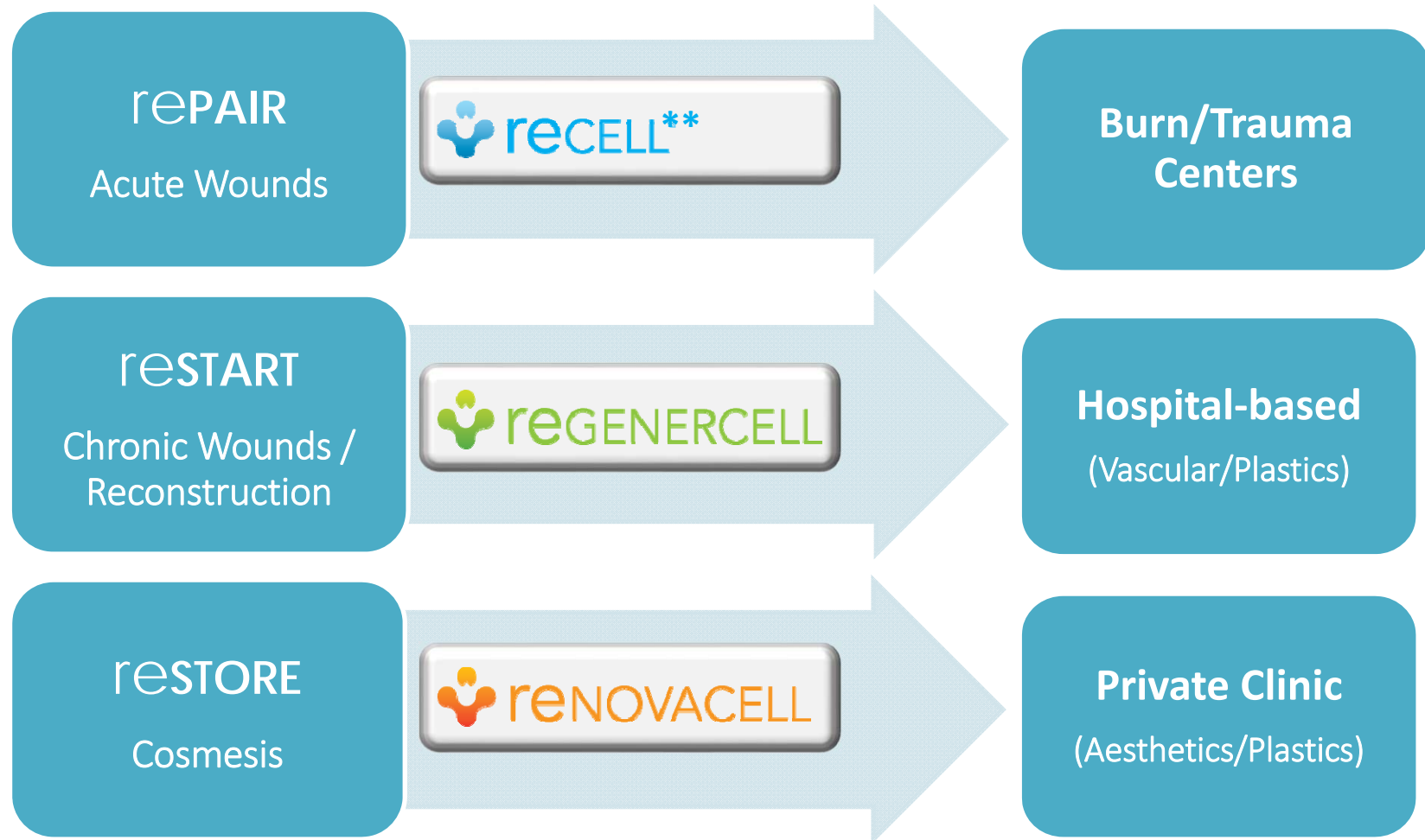
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Historical Challenges

- **The clinical indications targeted cannot be met with a single product**
 - Different aspects of the platform technology's mechanism of action feature more prominently in different clinical areas
 - Key messages must vary according to unmet need in each clinical area
- **Limited progress with US regulatory trial in burns**
- **Limited treatment area in burns**
 - The current ReCell device is limited to treatment of 320cm² (A5), which represents less than 2% of the total body surface area of an average adult male, however cost-effectiveness is achieved primarily for burn patients with larger injuries
- **A single product across disparate clinical areas limits partnering opportunities**



Launch of focused Regenerative Products



****High-capacity: for treatment up to 1,920 cm² (from 320 cm²)**



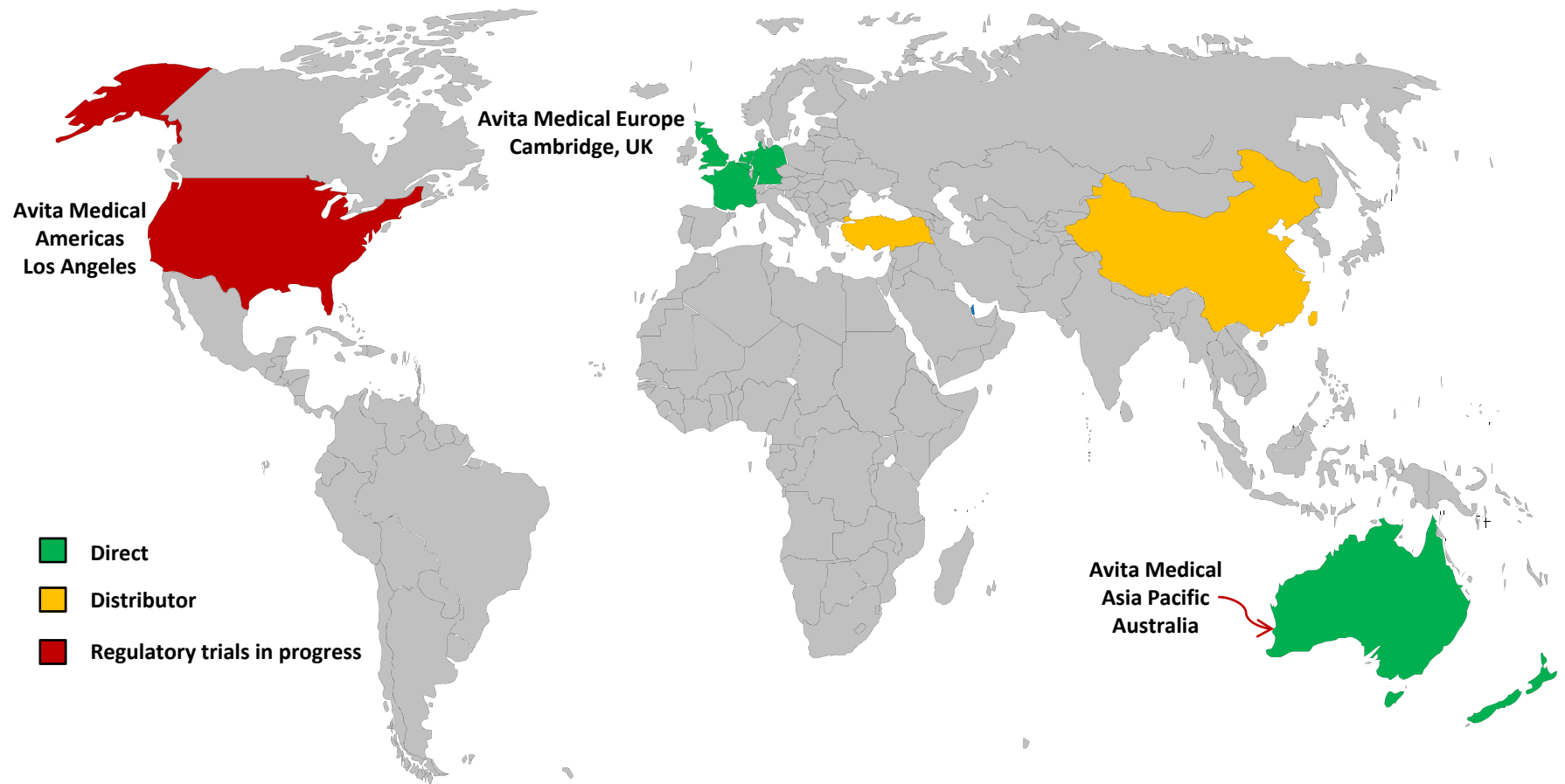
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Clarity Achieved with FDA means Defined Development Path Forward

- **Approved expanded evaluation of ReCell in burns and broadened eligibility criteria for study participants**
 - Resolved historical delays with recruitment
 - Positions ReCell for wider commercial opportunity
 - Trial participation now possible for much wider audience, including children
- **Trial will now address more extensive and severe burn injuries**
 - Supports ReCell approval in US
 - Supports marketing outside US
 - Addresses, in part, NICE guidance in UK
- **Historical development timeframe issue(s) now resolved**
 - Clarity achieved around regulatory approval protocol and timeline



Global Distribution



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Strategic Partnering Initiative



- Deliver Product
- Build Evidence Base
- Secure Approvals
- Demonstrate Commercial Success
(selected markets)

Pursue Commercial Partnerships

(By Indication / Call point / Geography)



examples of key players in selected markets - for illustration purposes only



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Respiratory Product Line: Update Summary

- Management explored divestiture options and has now resolved to reinvigorate the line with renewed focus and specific initiatives
- An increased investment in the line with the following initiatives is anticipated to stimulate additional revenue, as the respiratory line experienced a revenue drop of 8% from prior year
 - Building an AUS East Coast based sales team
 - Increase cooperative advertising budget
 - Pricing programs
 - Product Innovation
 - New focus on Primary Care GP's
 - Partnerships with local Asthma Foundations
 - Increased presence amongst community groups



How the past 12 months represent a
transformational period



Meaningful Progress Achieved

Clinical – delivering on high-level evidence (randomised controlled trials, RCTs)

○ **Acute Wounds**

- Revised US Burns RCT aligns with USP; in addition to regulatory approval, will support NICE data requirements and clinical marketing worldwide
- US Compassionate Use Cohort (not RCT) **MILESTONE ACHIEVED**
- Entered into agreement for collaboration with Walter Reed National Military Medical Center for trauma pilot study (using non-dilutive funding) **MILESTONE ACHIEVED**

○ **Chronic Wounds**

- Success in clinical feasibility work led to ongoing RCT in treatment of venous leg ulcers, nearly 60% enrolled toward target

○ **Aesthetics (repigmentation)**

- Release of statistically significant repigmentation results in vitiligo RCT, Netherlands Institute for Pigment Disorders (IPCC 2014)
- Award winning presentation of statistically significant result in hypopigmented scar RCT, Aust (World Congress for Pediatric Burns 2014 & ISBI 2014)



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Meaningful Progress Achieved (continued)

- **Sales & Marketing resources restructured to drive strategy**
 - Added marketing personnel
 - Built out new UK sales staff
 - New USPs focused on clinical unmet needs and viable opportunities
 - New, differentiated products launched, with associated re-branding and accompanying collateral, including high capacity ReCell **MILESTONE ACHIEVED**
 - Product no longer requires the hassle of refrigerated storage **MILESTONE ACHIEVED**
 - Market Research / Procedural Heat Maps generated
 - New website launched
 - Social Media reboot: Twitter / Facebook / YouTube / LinkedIn
- **Sales & Finance**
 - Cost Management provides 36% improved net cashflow result (\$3M)
 - Operating Costs reduced \$2.4M (burn rate at \$1.6M/Qtr.)
 - ReCell revenue growth of 5% in a restructuring year
 - Reinvestment in Respiratory Product line
 - Receipt of \$1.4 Million R&D Tax Incentive **MILESTONE ACHIEVED**



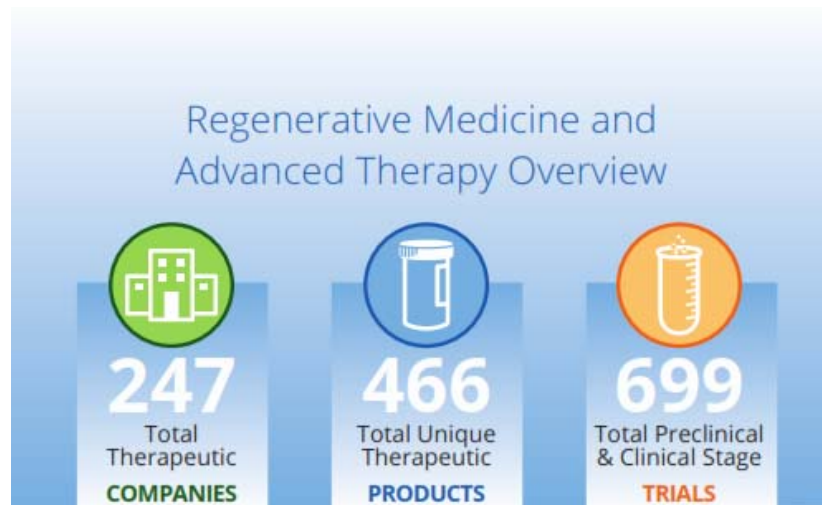
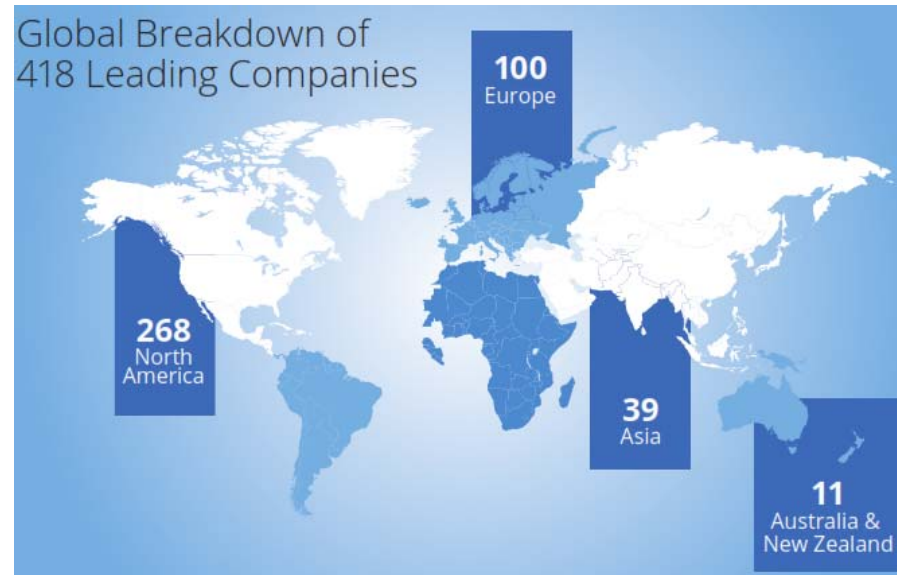
Understanding the “Avita Opportunity” Avita is Uniquely Positioned for Growth



Regenerative Medicine at a Glance

It is estimated that there are more than 700 companies worldwide with a regenerative medicine focus

The Alliance for Regenerative Medicine considers 418 of those companies as leaders in the space



There are 247 therapeutically focused companies in the space



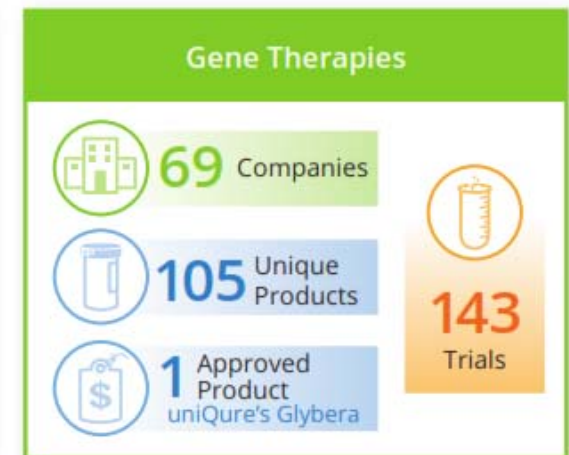
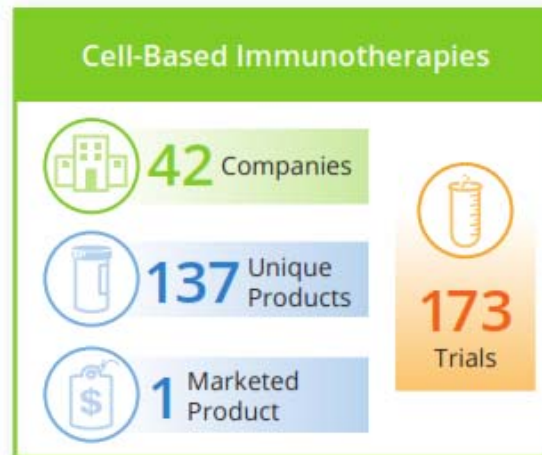
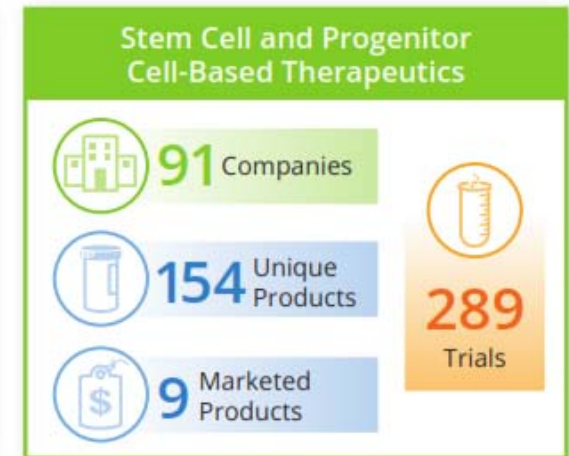
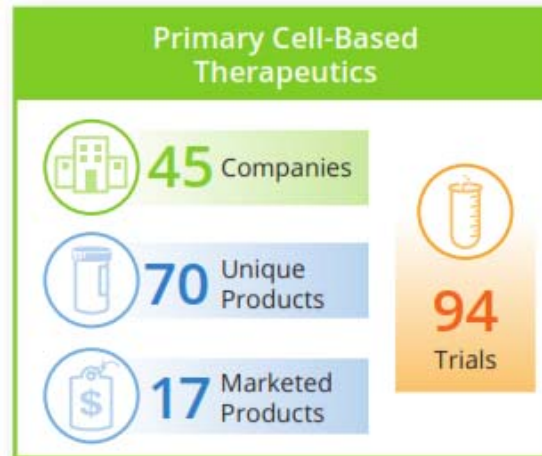
2014 Regenerative Medicine Annual Industry Report, Alliance for Regenerative Medicine

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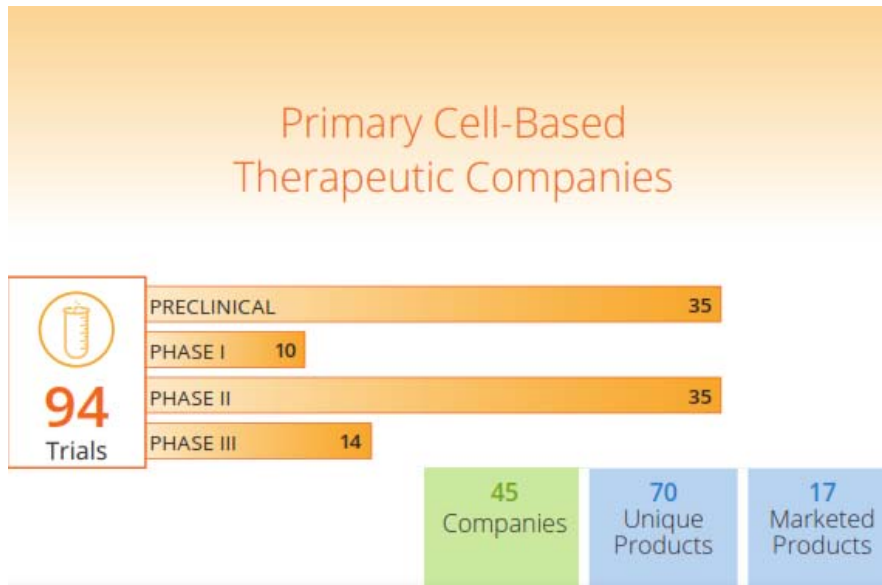
Our Standing in the Regenerative Medicine Space

Cell-Based Therapeutics

- Avita's Regenerative platform spans Primary Cell and Progenitor Cell Therapeutics
- Of the 247 companies in the Regenerative Medicine Therapeutic space there are only 28 marketed products
- ReCell has a first-mover advantage of being one of those products



US Phase III Status (Phase IV outside US)



- There are 383 clinical trials progressing in the Primary Cell-Based & Stem/Progenitor Cell-Based segments
- Only 25 of those trials are in Phase III (6.5%)
- ReCell's recently modified US Phase III burns trial now paves a clear pathway



Pharmaceutical and Large-Cap Biotech Perspective on Regenerative Medicine

Pharma and Large-Cap Biotechs Engagement in Regenerative Medicine



Survey Respondents

Allergan, Amgen, Baxter, Biogen Idec, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Johnson & Johnson, Merck Serono, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi-Genzyme, Shire

“We are actively looking for a partner in the cell therapy business and are open to any relationship from partnership to divestiture.”

“We realize it’s a frontier technology beyond a five year time horizon and we don’t want to miss the boat. Our company is engaged in various levels and resources are internally devoted.”



A highly active space: Recent M & A Activity

Deal Type	Company(s)	Total Deal Value	Upfront Payment	Date
Collaboration	Tengion / Celgene	\$15M	\$15M	7/1/13
Merger	Capricor / Nile Therapeutics	NA	-	7/8/13
Commercialization Agreement	uniQure NV / Chiesi Farmaceutici	\$39.8M	\$39.8M	7/9/13
Collaboration	Stratatech / BARDA Contract	\$47.2M	-	7/31/13
Acquisition	Mesoblast / Osiris Stem Cell Therapeutic Business	\$100M	\$50M	10/11/13
Licensing Deal	Cytori Therapeutics, Inc. / Lorem Vascular	\$500M	\$24M	11/4/13
Licensing Deal	Pluristem / CHA Biotech	\$10.4M	\$10.4M	12/17/13
Acquisition	Intrexon / Medistem	\$26M	-	12/20/13
Collaboration/Licensing Deal	Capricor / J&J	\$325M	\$12.5M	1/6/14
Collaboration	Sangamo / Biogen Idec	\$320M	\$20M	1/9/14
Acquisition of Dermagraft	Organogenesis Inc. / Shire	\$300M	0	1/17/14
Acquisition	Sillajen / Jennerex	\$150M	-	3/17/14



Market Opportunity

Effectively unlimited...

Selected Indications <small>e.g., excludes plastic and maxillofacial surgeries</small>		Opportunity				Market Size*
		US <i>pop. 316M</i> (11.4% diabetes ¹)	UK, FR, DE, IT <i>pop. 271M</i> (8% diabetes, avg ¹)	Aus <i>pop. 23M</i> (5.1% diabetes ¹)	China <i>pop. 1.4B</i> (9.3% diabetes ¹)	
Chronic Ulcers	DFU ²	9.0M	5.5M	0.3M	31.6M	\$46.4B
	VLU ³	3.2M	2.7M	0.2M	13.6M	\$19.7B
Burns annual admissions		40K ⁴	42K ⁵	8.6K ⁶	3.4M ⁷	\$3.5B
Aesthetics annual procedures ⁸		1.7M	585K	117K	157K	\$2.6B
Vitiligo <i>0.1% to 2% of pop.</i> ⁹		316K	27K	23K	1.4M	\$2.0B
TOTAL*		\$14.3B	\$9.1B	\$0.7B	\$50.1B	>\$70B

*assumes one device @ \$1,000 per patient ASP

¹ International Diabetes Federation (IDF) Diabetes Atlas, Sixth Edition (2014)

² [Lifetime incidence: 25% of diabetics] Singh N, Armstrong DG, Lipsky BA. "Preventing foot ulcers in patients with diabetes." JAMA 293, no. 2 (2005): 217-228.

³ [Prevalence: 1% of pop.] Humphreys ML, Stewart AHR, Gohel MS, Taylor M, Whyman M R, and Poskitt K R. "Management of mixed arterial and venous leg ulcers." British Journal of Surgery 94, no. 9 (2007): 1104-1107.

⁴ American Burn Association 2013 Fact Sheet (www.ameriburn.org)

⁵ Brusselaers N, Monstrey S, Vogelaers D, Hoste D, Blot D. "Severe burn injury in Europe: a systematic review of the incidence, etiology, morbidity, and mortality." Crit Care 14, no. 5 (2010): R188.

⁶ Australian hospital statistics. Australian Institute of Health and Welfare. (2012)

⁷ Peck MD. Epidemiology of burn injuries globally www.uptodate.com

⁸ ISAPS 2013 International Survey on Aesthetic/Cosmetic Procedures Performed (dermabrasion, resurfacing, facial rejuvenation, botulinum toxin)

⁹ Alkhateeb A, Fain PR, Thody A, Bennett DC, Spritz RA. "Epidemiology of vitiligo and associated autoimmune diseases in Caucasian probands and their families." Pigment Cell Research 16, no. 3 (2003): 208-214.



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A look forward



The Plan Moving Forward

A clear path ahead, strategic and targeted execution



**Expand ReCell use
in Acute Wounds
(burns /trauma)**

Key Drivers:

- US Burns RCT
 - ✓ Will support application for US FDA approval of ReCell
 - ✓ Will support outside-US marketing efforts
- New, high-capacity ReCell
- Repositioning for routine use in grafting procedures
- US Trauma Pilot RCT (funded)



Capitalise on Aesthetics

Key Drivers:

- Recently completed , ongoing and planned RCTs in vitiligo, hypopigmentation and rejuvenation
- Enhanced clinic support, including clinic revenue modeling and patient consultation kit to facilitate clinicians' promotion of ReNovaCell



**Continue to develop
Chronic Wounds**

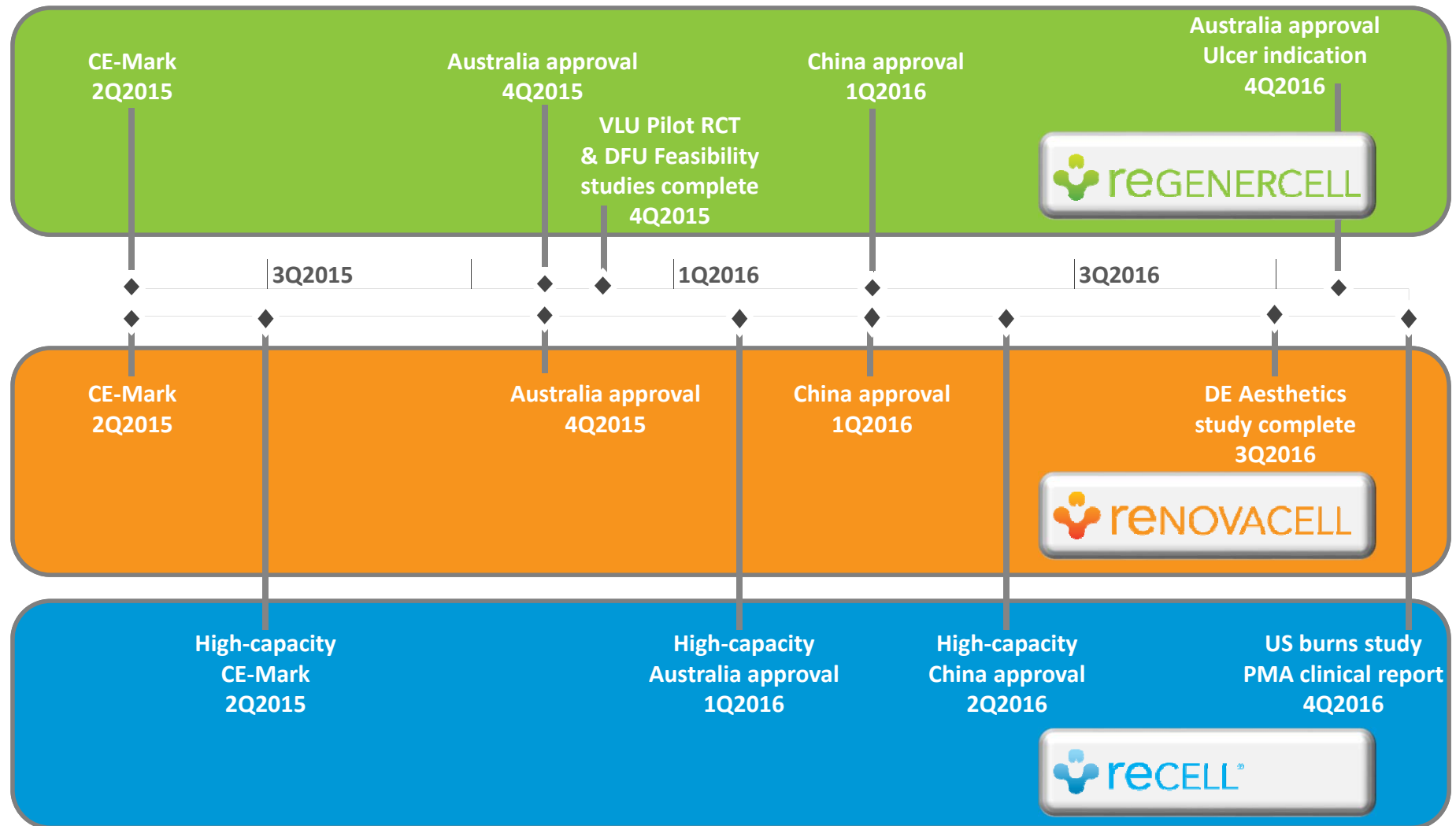
Key Drivers:

- Venous Leg Ulcer Pilot RCT
 - ✓ Will support clinical marketing in CE-mark countries
 - ✓ Will support applications for expanded indications in Australia and China
 - ✓ Will support FDA application for pivotal RCT in US
- Feasibility work in DFU, to support future RCTs



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Key Upcoming Milestones



Continuous execution of branding improvements and further development of robust clinical evidence base

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Today's Avita: Well-Positioned for Growth

- Supportive institutional shareholders
- Qualified and aligned Board
- Experienced and committed management team
- **Transformative platform technology & focused commercialisation strategy**
 - Now on a clear course for FDA approval for key burn indication
 - Gaining traction in the marketplace
 - Expanding Sales & Marketing / Business Development team
 - Working toward strategic partnerships
- **Groundwork established for overseas institutional introduction in 2015**
 - US-based IR firm retained October '14 to facilitate raising of overseas profile
- Avita is passionately focused on increasing value for shareholders



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