

Stimulating Immunity to Heal Infections

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Major Problem: Antibiotic Resistance

Infections are
untreatable

- Resistant bacteria
- Biofilm formation
- Difficult to access bacteria



8% of joint infection patients
die within one year¹

\$20B

US
economic
burden²

4.95 M
associated deaths⁴

3,000,000
resistant infections
in the US annually²



13 hospital days per
resistant infection³

\$50,000 cost
increased
per patient³



¹Journal of Bone and Joint Infection 2019. 4 (4) 198-202

²CDC AR Threats Report 2019 US Dept HHS

³Seminar in Plastic Surgery 2016. 30:66-72

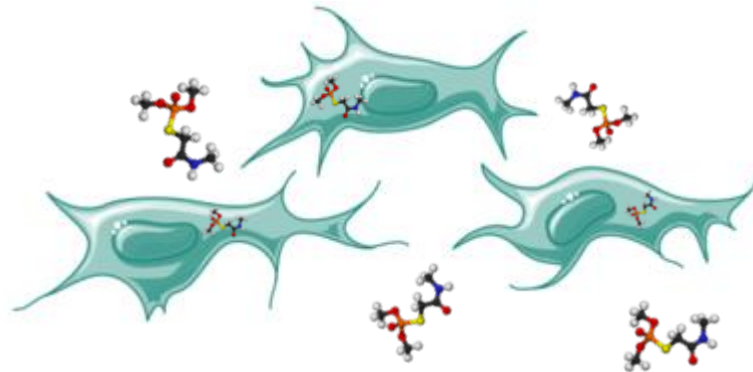
⁴Lancet 2022. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

Preparing cells to fight infections

1. Mesenchymal Stromal Cell (MSC)

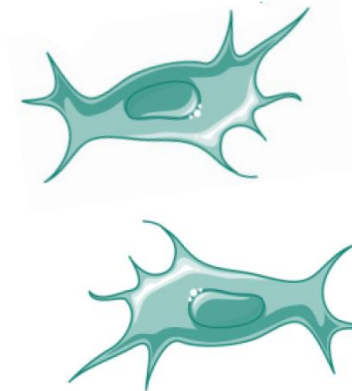


2. Train cells to recognize infection



Proprietary Process + Activating Agent

3. Treat Infections



- Infection targeting^{1,2}
- Direct bacterial killing^{1,2}
- Enhanced bacterial killing by immune cells²
- Immune cells promote healing and repair¹



VCT-101 Approach

Evidence from Pet Dogs



Infected paw



Healed paw

15 dogs enrolled *following* one or more failed antibiotic treatments¹

9 infections resolved completely

4 infections responded and improved

2 infections were unchanged



87%
fully resolved
or significantly
improved

Resistant infections having persisted for as long as 24 months were **successfully treated.**

Resolved multiple germs:
Staphylococcus, E. coli,
Pseudomonas, Klebsiella,
Corynebacterium¹



US 20180360885A1

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(12) **Patent Application Publication** (10) **Pub. No.: US 2018/0360885 A1**

Dow et al. (43) **Pub. Date: Dec. 20, 2018**

(54) **ACTIVATED STEM CELLS AND SYSTEMIC TREATMENT METHODS FOR INFECTED WOUNDS**

Publication Classification

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A61P 17/02 (2006.01)

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 CPC *A61K 35/28* (2013.01); *A61K 9/0019* (2013.01); *A61P 17/02* (2018.01); *A61P 31/04* (2018.01)

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(86) PCT No.: **PCT/US2016/065392**

§ 371 (c)(1),
(2) Date: **Jun. 6, 2018**

Related U.S. Application Data

(60) Provisional application No. 62/264,077, filed on Dec. 7, 2015.

(57) **ABSTRACT**

Provided herein are compositions containing an infusion ready population of activated, allogeneic mesenchymal stem cells and one or more pharmaceutically acceptable carriers, diluents, or excipients. Also provided are methods of treating infected wounds in mammals by administering an effective amount of activated mesenchymal stem cells to the mammal.

Intellectual Property

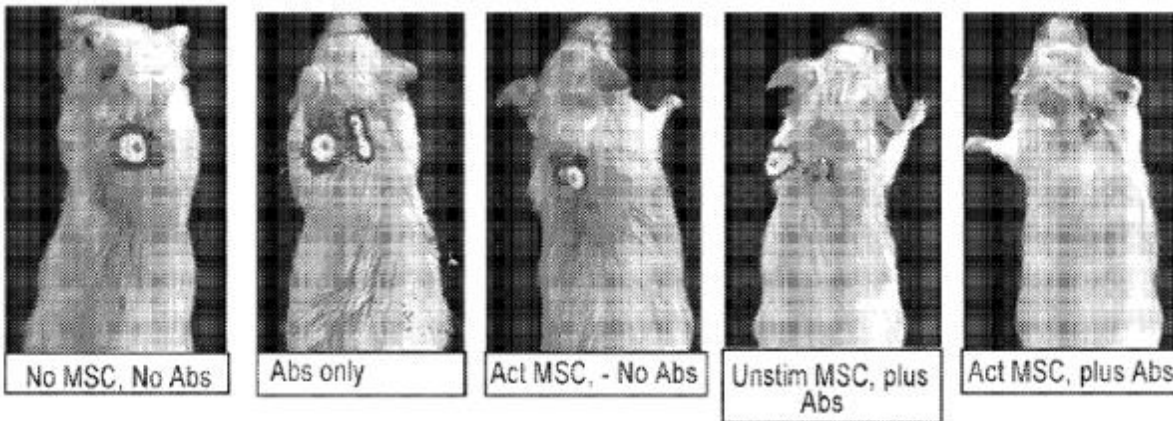
PCT application filed Dec 7, 2016

- PCT/US2016/065392
- US, Europe, Japan, Singapore, Korea, China


Claims summary:

- Composition of stem cells treating infection
- Systemic infusion for clinical benefit
- Augmentation of antibiotics

Global license from Colorado State University



Broad Development Pipeline

Disease State	Products	Concept	Pre-Clinical	IND	Phase I	Phase II/III	BLA
Antibiotic Resistant Bacterial Infections	VCT-101	Orthopedic Infection					 Potential FDA Accelerated Approval
		Chronic Wounds					
	Pneumonia						
	VCT-102	Direct injections					
Innate or Healing Tissue Dysfunction	VCT-201	Osteo Arthritis					
		ARDS					
Innate Immune Deficiencies	VCT-301	Oncology Therapies					

VCT-101 & VCT-201 refer to cellular therapy candidates with specific therapeutic functions. IND is Investigational New Drug (application with US FDA); COPD is chronic pulmonary disease; ARDS is acute respiratory distress syndrome.

Leadership Team



Ethan Mann, PhD, MBA
Co-founder, CEO, Director
Infectious Disease Expert, Fund Raising,
Previous Start-up Exit, Gov't Grant PI



Mike Handley, MBA
Director
Pharmaceutical Executive
CEO of Statera, Inc.



Steve Dow, PhD, DVM, MS
Co-founder, CSO, Director
Immunotherapy expert,
Start-up CTO experience



Frank Barry, PhD
Director
Cell Therapy Expert,
Regenerative Medicine Institute

Board



Dave Desmond, eMBA
CFO
Growth, Strategy, Start-ups
Fund Raising, Scale to Revenue



Aline Betancourt, PhD
Founder and CSO Vitabolus, Inc.
Stem Cell Expert
Previously exited MSC start-up inventor



Douglas Looker, PhD
VP of Operations
Pharma manufacturing, Regulatory,
Clinical Development, Production GMP



Laura Damioli, MD
University of Colorado
Asst. Professor, Medicine-Infect. Disease
Director, Ortho ID Subdivision
ID Lead Provider, Limb Restoration Team

Management



Jason Stoneback, MD
University of Colorado
Assoc. Professor, Chair, Trauma and Fracture Surgery
Director, Limb Restoration Program

SAB



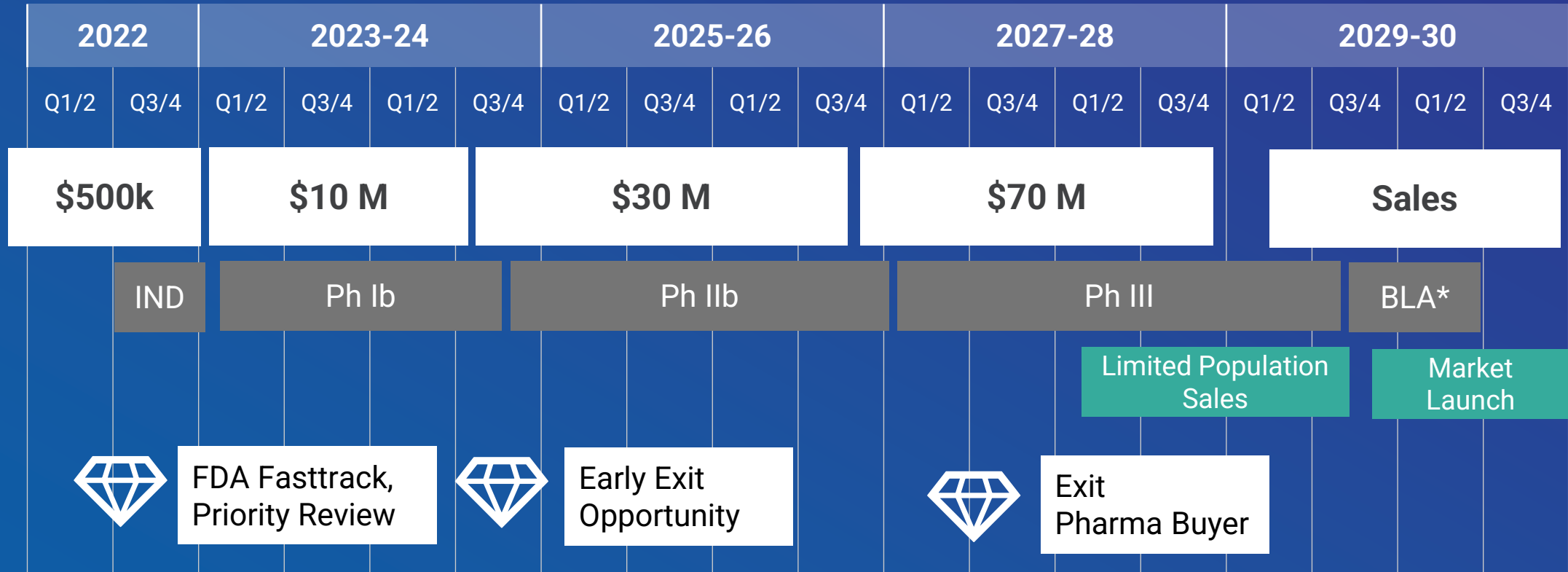
Competitive Positioning

Approach	Companies, Providers	Curative Efficacy	Narrow to Broad Application	Patient Accommodation	Therapeutic Novelty	Pricing Power
Activated Stem Cell Therapy	Validus Cellular Therapy	++++	++++	+++++	+++++	+++++
High dose/Long term Antibiotics	Pfizer, Merck, Novartis, Sanofi, GSK, J&J1	+++	++	+	++	+
Revision Surgery	Physicians	+++	++++	+	+	+
Phage Therapy ³	Phagelux, Ampliphi, PhagoPied	++	+	++++	++++	++
Minimally-invasive treatment (ultrasound, hyperbaric O ₂)	Perry Baromedical, ETC Biomed. Sys.	++	++++	++++	+++	+++
Amputation	Physicians	+++	++++	+	+	+
Vaccines	Sanofi, Valneva, Pfizer	Unknown	+	+++++	++	+
Anti-biofilm enzymes, Novel antimicrobial targets	ProclaRx, Next Science, KANE, Amicrobe	++	+++	++	+++	++

+ corresponds to satisfaction of the category, more "+" is stronger



Product Roadmap Starting with \$500k Seed Financing



***FDA 351: Biologic License Approval (BLA):**
Market exclusivity for 12 years.



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Treating Untreatable Infections

- Compelling pre-clinical data
- Ready for first-in-human clinical trial
- Well defined regulatory path