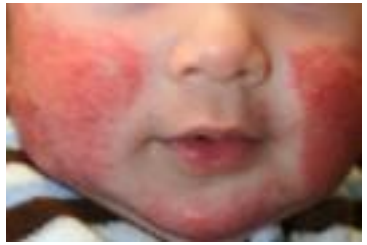
Healthier skin through healthier healing

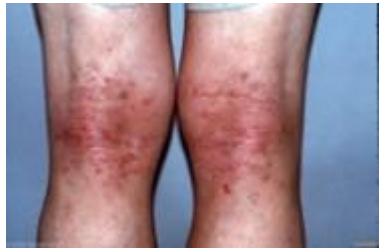
A safe and effective solution for atopic dermatitis

Mike J. Davies, MD, FRCS
CEO & Founder, Carocell Bio Limited
mike.davies@carocellbio.com
+1 210 775 2161

Atopic dermatitis (AD) - the problem

- Inflicts 15-20% children and 1-3% of adults worldwide, 10% of US population (1,2)
- "Mothers hate putting steroids on their child's face" (3)
- Longer-term and poorly managed Atopic Dermatitis (AD, eczema) can cause premature aging of the skin[1]
- Current solutions are ineffective or have significant problems, for example:
  - First line – topical ointments and creams – contain no medication
  - Second line – topical steroids – toxic and unsuitable for treatment of >30 days
  - Third line – topical calcineurin inhibitors – "black boxed" in USA
- $21 billion market for mild-moderate AD (4)





1. Nutten S, 2015;
2. Eichenfield LF et al, 2014
3. Personal comment Prof. Anne Dickinson, Newcastle upon Tyne, UK
4. FinancialNewsMedia.com News Commentary, October 2021

"black boxed" = is the most serious type of warning mandated by the U.S. Food and Drug Administration (FDA).

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Our solution is a novel super-peptide: JEL3108

- Topically applied *peptide* inhibitor
- Deliver to target area in skin
- Significantly reduces inflammation markers and prevents activation in cell studies – and now in human AD tissue biopsies
- ***Delays aging of the skin***
- Safe
- Rapidly broken down into naturally occurring amino acids
- Only works at site of application
- Patent protected:
  - 3 granted (US10293024, JP6566947, P3033094)
  - 2 in progress

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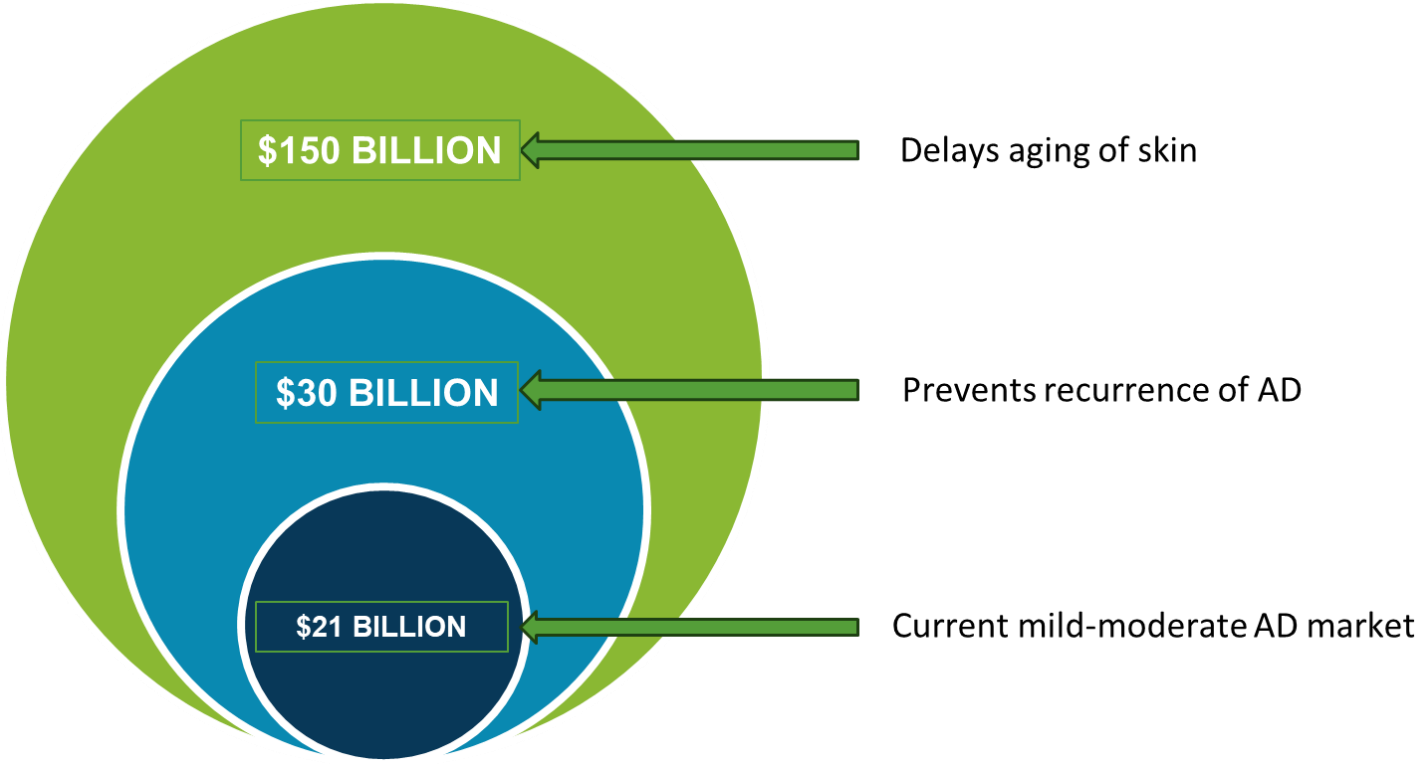
Atopic Dermatitis (eczema) - Market

- $21 billion market for mild-moderate AD [5]
- No single safe & effective solution on market
- None has all the advantages of JEL3108



Global market size for AD treatment

5. FinancialNewsMedia.com News Commentary, October 2021

Atopic dermatitis (eczema) - Competition

- **Topical corticosteroids (TCS)**
  - Range of potencies to cater for different disease severities
  - Worries over side effects; “corticophobia”
- **Protopic (tacrolimus)**
  - Topical calcineurin inhibitor (TCI) available in 0.03% and 0.1% strengths
  - Transient site application pain
  - Black-boxed in USA
- **Elidel (pimecrolimus)**
  - Topical calcineurin inhibitor (TCI) for mild-to-moderate patients
  - Transient site application pain
  - Black-boxed in USA
- **Eucrisa (crisaborole)**
  - Topical PDE-4 inhibitor for mild-moderate patients
  - Persistent site application pain, expensive
- **Systemic immunomodulators**
  - Includes cyclosporine, azathioprine, methotrexate, and mycophenolate mofetil
  - Large side effect profiles
- **Dupixent (dupilumab)**
  - Anti-IL4 receptor subcutaneous injection once every two weeks
  - Conjunctivitis the most common side effect
- **No single safe & effective solution**
- **Many small molecule drugs in development / recently marketed**
  - JAK inhibitors
  - PDE4 inhibitors
  - 5-LO inhibitors
  - TRPVI RAs
  - Aryl hydrocarbon RAs
  - Others

All have side effects and cannot be used long term.
Carocell Bio’s novel peptide ‘cure’ for AD has the potential to provide safer and more effective options for patients with mild-to-moderate AD

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Source: Global Data

Clinical and Regulatory Pathway

- Adaptive regulatory and clinical strategy outlined
  - Discussed with regulatory consultants
    - 2 years to Regulatory Approval for clinical trials (IND)
  - Adaptive clinical development plan outlined
    - To gain all endpoints more rapidly
  - Gain safety and clinical efficacy in first clinical trial
  - Clinical efficacy:
    - JEL3108 works
    - JEL3108 prevents recurrence of the disease
    - JEL3108 delays aging of the skin

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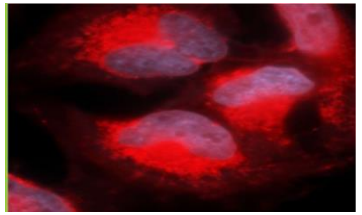
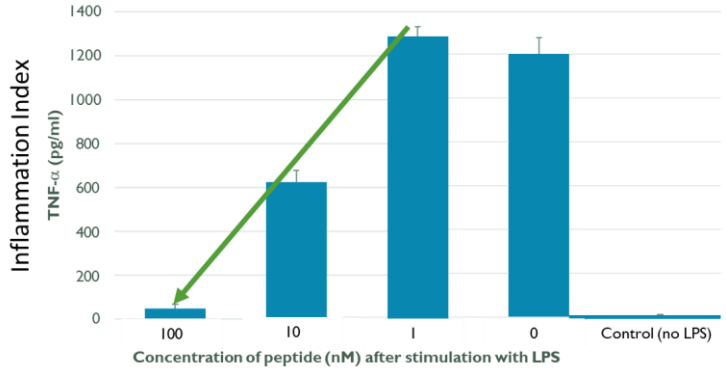
5. FinancialNewsMedia.com News Commentary, October 2021

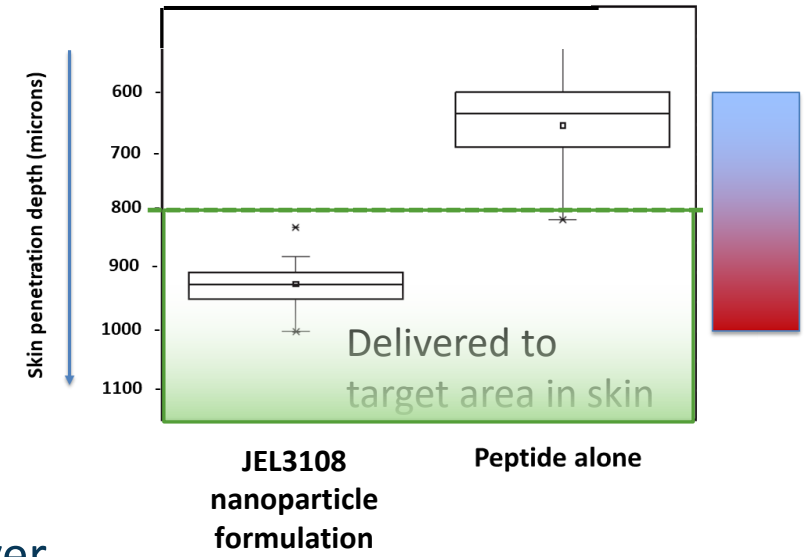
Use of Funds to date

- Founded Oct 2018
- Finance rounds:
  - Innovate UK grant - $475,000
  - Seed funding - $850,000
  - Founder investment - $650,000
- Deliver JEL3108 into cells
- Can deliver into target area of skin
- JEL3108 broken down into naturally occurring amino acids
- Significantly reduce inflammation
- Prevents activation of inflammation
- Highly specific (150-fold selective over p38β)
- Works in human AD biopsy samples

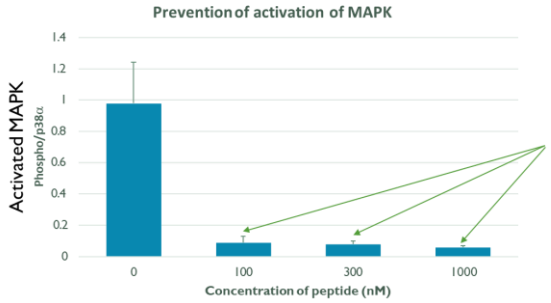


Delivery into cell





Epidermal-dermal junction ~0.6-1mm



All doses tested - [100nM (the minimum effective dose (from Slide 10) and above] - prevent the activation of inflammation (Phospho/p38a)

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Team: Comprehensive tech. translation and market access experience

John Nicholson, PhD

Chairman

MA, University of Cambridge

International experience in pharma from start-up to the market

Advisory Board of Northwest Business Fund ($175m)

Chairman and CEO of Gentronix to 2019

Dr Mike Davies, MD, FRCS

CEO & Founder

MD, Edinburgh University Fully rained as surgeon

>25 years experience in drug development

Pfizer, AstraZeneca, Shire and biotechnology companies

Taken new medicines from ideas to the market

Invested over $600,000 and sweat equity into Carocell Bio

Full time

Pfizer, Shire, Renovo, AstraZeneca, serentis, Blueberry Therapeutics, QUINTILES

Search commenced

Financial Director

Professor Anne Dickinson, PhD

Emerita Professor, Newcastle University and Director of Newcastle Cellular Therapies Facility

Professor Yvonne Perrie, PhD

Drug Delivery, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow

Professor Antony Sedgwick, PhD

Experienced biotech executive with over 40 years of experience in the sector

Mr David Black

Marketing Consultant

Director owner of Onside Creative Director of several manufacturing businesses

30 years of experience in Marketing and Advertising

Dr Priya Kalia, BSc, PhD

Director of Communications

David Browning

Strategic Advisor

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Investment and Use of Funds

Cost	Year 1	Year 2	Year 3	Year 4	Total
Formulation & GMP manufacture	$500K	$2M	$1M	$1M	
Staff/consultants/overheads	$600K	$1M	$2M	$2M	
Toxicology/safety/lab costs	$400K	$2M	$2M	£2M	$38M
Regulatory (IND)	$300K	$1M	$1M	$1M	
Clinical costs	$200K	$2M	$8M	$8M	
TOTAL	**$2M**	**$8M**	**$14M**	**$14M**	

Sale/license $1.2B[6]

Pre-IND

IND

Clinical Proof of Concept

Exit opportunities include:

- IPO after IND approval (end Year 2)
  - Valuation at this time c.US$100 million (6)
  - Raise money for Adaptive Clinical Proof of Concept trial
- License deal after Adaptive Clinical Proof of Concept (end Year 4)
  - Valuation at that time c.US$1.2 billion (6)

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6. Valuation and Returns of Drug Development Companies: Lessons for Bioentrepreneurs and Investors. DT Michaeli, HB Yagmur, T Achmadeev, T Michaeli. Therapeutic Innovation & Regulatory Science (2022) 56:313–322. https://doi.org/10.1007/s43441-021-00364-y

Summary

- Carocell Bio's new peptide will not only cure AD - it could also *significantly delay aging of the skin – and reduce surgery*
- Seeking $10 million over 2 years to IND approval ($100m valuation)
- **Contact:**

Dr Mike Davies
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Appendix

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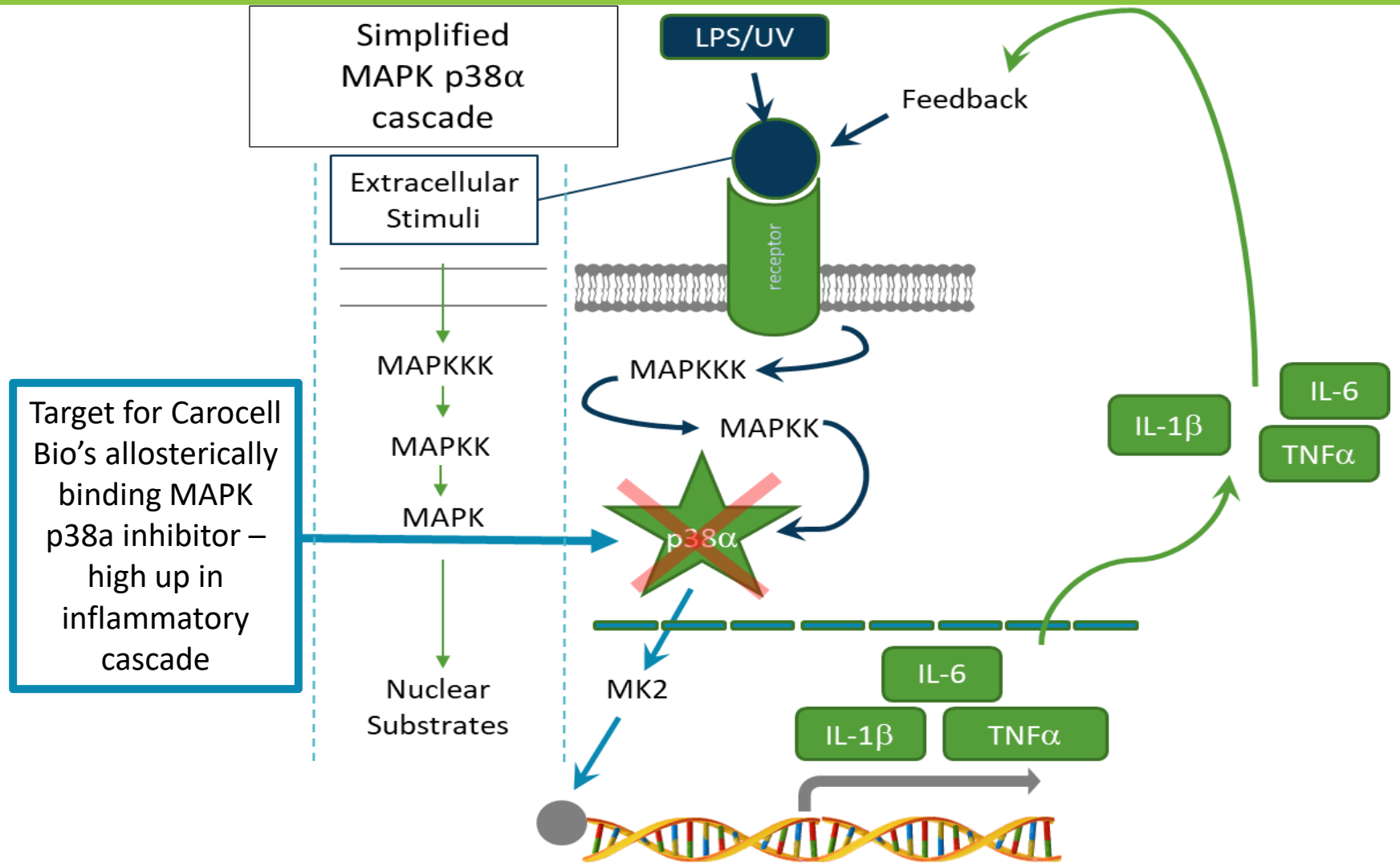
Mechanism of Action



p38α is a key modulator of the Inflammation cascade

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