A pioneering regenerative medicine platform in ophthalmology and tissue repair

Shareholder Update

Regeneus Ltd
ASX:RGS

September 2023

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Background

- On 28 April 2023, Regeneus announced that it had signed a non-binding term sheet to merge with Cambium Medical Technologies, LLC ("CMT"), based in Atlanta, Georgia, USA

- CMT was founded in 2013 as an ophthalmology-focused spin-off from Emory University, Atlanta, GA
- The Company has successfully completed preclinical studies, a Phase 1/2 trial in dry eye disease ("DED"), and is now preparing for two Phase 3 trials in DED
- The two Phase 3 trials are expected to be registration enabling, and CMT already have Investigation New Drug (IND) applications approved by the FDA
- CMT has raised US$ 9.2M in equity and non-dilutive funding to date

- Regeneus and CMT are working towards signing binding merger documentation, and the transaction is expected to close later in CY 2023, subject to signing binding documentation and obtaining the required approvals
- Regeneus expects to sign binding documentation in October 2023 and hold a General Meeting in November 2023
- The merged company will be renamed to Cambium Bio Ltd ("Cambium Bio", "Cambium")

Cambium Bio overview

Proforma clinical assets

The merger will create a pioneering regenerative medicine platform focused on ophthalmology and tissue repair

Product	Elate Ocular®	Progenza	Sygenus
Technology	Aurarix® Fibrinogen-depleted human platelet lysate ("FD-HPL")	Allogeneic adipose-derived mesenchymal stem cells (AD-MSC) with bioactive secretome	AD-MSC bioactive secretome for topical administration
Lead indication	Chronic Dry Eye Disease	Knee osteoarthritis	Pain and wound healing
Development stage	Phase 3 ready	Phase 1 completed	Preclinical
Current status	Two Phase 3 IND applications approved by the FDA in the USA	Seeking licensing partners	Seeking licensing partners

Cambium Bio overview

Proforma top management and shareholding structure

Top management

Karolis Rosickas
Chief Executive Officer

- Co-founder of cell therapy CDMO SingCell, Singapore
- Co-founder of digital therapeutics company OME Health, London, UK
- Vice President, Healthcare Investment Banking, HSBC, London, UK
- Finance Director, Danone Early Life & Clinical Nutrition, Baltic States
- Regional Treasurer for Asia at the International Society for Cell and Gene Therapy (ISCT)
- MS(c) in Biotechnology at Northeastern University, Boston, MA
- MBA at IESE Business School, Barcelona, Spain

Terence Walts
Chief Operating Officer

- Co-founder of Cambium Medical Technologies in 2013
- CEO of 3Ti (automated blood analyzer start-up)
- CEO of Refocus Group (ophthalmic device start-up)
- CMO of Autonomous Technologies (refractive surgery start-up)
- VP WW Sales, Marketing and BD at Novartis (CIBA Vision)
- MBA at The University of Notre Dame, Indiana
- BS in Marketing at Indiana University, Indiana

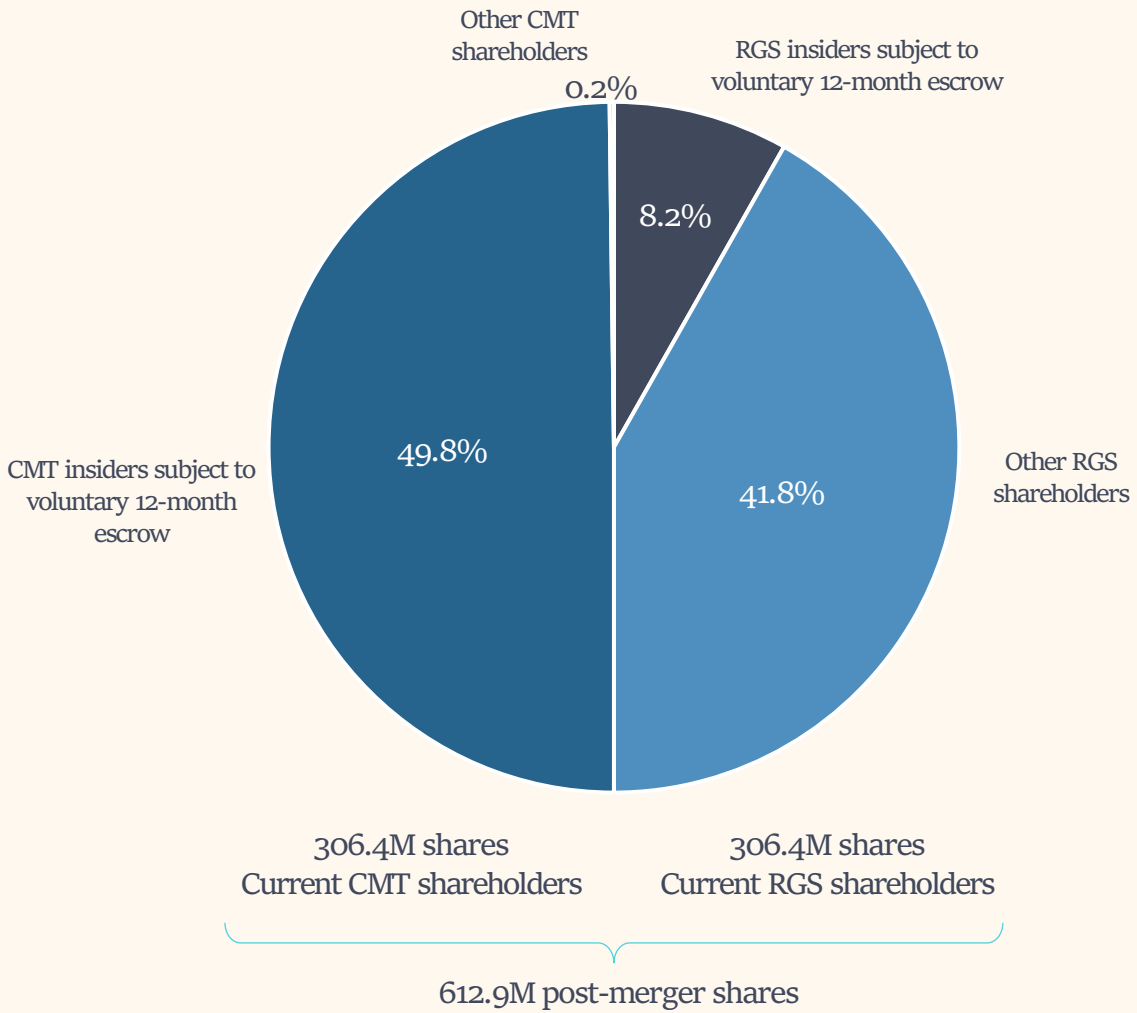
Dr. Edmund Waller, MD, PhD
Chief Scientific Officer

- Co-founder of Cambium Medical Technologies in 2013
- Professor of Medicine, Pathology & Hematology/Oncology at Emory University, Atlanta, GA
- Multiple other roles at Emory University, Atlanta, GA
- PhD at The Rockefeller University, New York City, NY
- MD at Cornell University Medical College, Ithaca, NY
- BA at Harvard University, Cambridge, MA

Dr. Neera Jagirdar, MD, MPH
Director of Clinical Dev.

- Joined Cambium Medical Technologies in 2017
- Over 15 years of experience in the design and conduct of experimental research studies and clinical trials in support of new product development and quality assurance
- MD at American University of Antigua, Osbourn, Antigua and Barbuda
- MPH at American Public University, Charles Town, WV
- BA at Boston University, Boston, MA

Indicative percentage post-merger shareholding structure



Cambium's fibrinogen-depleted human platelet lysate platform technology Aurarix®

- Platelets are anucleate cells produced in the bone marrow and found in human blood, rich in growth factors, cytokines, and other bioactive molecules
- Aurarix® is pooled, enriched, fibrinogen-depleted, allogeneic human platelet lysate ("FD-HPL"), sourced from healthy donors
- The technology was exclusively licensed by CMT from Emory University, GA, USA, in 2013. License terms are in line with industry standards
- Aurarix® is protected by the core patent "Compositions, Uses, And Preparation Of Platelet Lysates" (US 9,688,959 B2) in key geographies worldwide with expiry in mid-2032
- To date, HPL has not been approved for any therapeutic use but has been used extensively as a supplement in cell culture processes:
  - Aurarix® FD-HPL technology has been sub-licensed to AventaCell, an affiliate of Cambium's strategic partner Zheng Yang Biomedical Technology (ZYBT) in Taiwan, to manufacture and commercialise stem cell growth supplements
  - CMT earns quarterly sub-license royalty revenue from ZYBT ($375k in the last 12 months). ZYBT is a ~10% shareholder in CMT and led its seed financing round in 2014
- Additionally, Aurarix® FD-HPL platform technology can be applied in various therapeutics markets and represents significant growth opportunities for Cambium Bio:
  - Orthopaedics, wound healing
  - Multiple indications in ophthalmology
- Cambium Bio's lead indication for Aurarix® technology is the treatment of chronic dry eye disease using the Elate Ocular® FD-HPL-based product

Aurarix® cell culture supplement Source: AventaCell

Dry Eye Disease overview

Definition and clinical presentation

- DED (Keratoconjunctivitis Sicca) is a multi-factor disorder of tears and ocular surface
- Loss of tear film homeostasis - failure to produce high-quality or sufficient tears
- May lead to visual disturbance, irritation, pain, corneal ulceration, conjunctival scarring, infection, and reduced quality of life (QOL)
- Associated with increased osmolarity and inflammation of the ocular surface

Burden of Disease (United States)

- 17M adults diagnosed with DED, corresponding to a prevalence of 6.8%*
- Additional 5-6M experience DED symptoms but have not been diagnosed
- $2B+ annual prescription drug expenditure

Source: American Academy of Ophthalmology (AAO), Ferrand (2017), Findlay (2018), Craig (2017), GlobalData DED Marketed Drugs report (2022), GlobalData "Dry Eye Syndrome" report (2018)
Note: * DED prevalence in certain Asian markets (China, Japan) is even higher at 20%+, Cai et al (2022)

Dry Eye Disease etiology

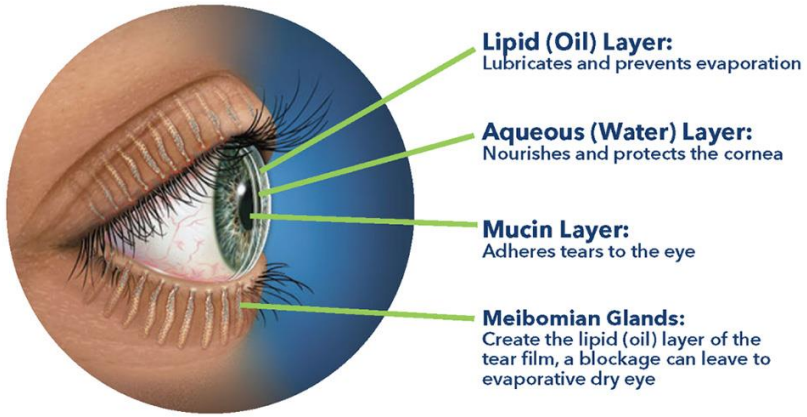
Contributory factors

- Age-related and hormonal changes
- Autoimmune disorders (e.g. Sjogren's, oGvHD, rheumatoid arthritis, lupus)
- Environmental (e.g. dry climate, computer work, smoke exposure, contact lenses)
- Medications (e.g. antihistamines, beta-blockers, antidepressants, anti-anxiety drugs)

Types of DED

- Aqueous deficient – reduced tear production from lacrimal glands
- Evaporative – Meibomian gland dysfunction (MGD) leading to poor tear quality (lipid deficient)
- Estimated 75-85% of DED caused by MGD

Natural tear film layers



Role of inflammation in DED

- Extensive peer-reviewed literature suggests chronic inflammation of the ocular surface and lacrimal gland contributes to DED pathogenesis
- Inflammation can contribute to dry eyes, by interfering with tear and/or lipid production
- Similarly, poor tear function can exacerbate inflammation response, creating a vicious cycle
- The role inflammation plays in both the development and propagation of DED has led to a development focus on anti-inflammatory and immunosuppressive topical treatments

Source: AAO, Ferrand (2017), Findlay (2018), McMonnies (2020), Baudouin (2019), Holland (2016)

Current treatment options for DED

Low — Severity of DED — High

Conservative Tx

- Behaviour modification
- Environmental modification
- Enhanced cleansing/hygiene

OTC treatments

- Artificial tears
- Lubricating ointments
- Omega-3 supplements

Office treatment

- Punctal plugs
- Thermal pulsation
- Autologous Serum Tears

Prescription drugs

- Corticosteroids
- Anti-inflammatories
- Immunosuppressive agents

Cambium Bio solution – Elate Ocular® biologic eye drops

"Off the shelf natural tear"

- Derived from enriched fibrinogen-depleted human platelet lysate
- Similar pH and osmolarity to normal tears, but higher overall protein content
- Contains enriched levels of regenerative factors (EGF, PDGF, TGFβ1), protease inhibitors, minerals and vitamins

- Supports improved ocular surface health
- Administered 4 times a day (QID)
- Improved allogeneic version of Autologous Serum Tears (AST)

Elate Ocular® is superior to validated Autologous Serum Tears concept with strong compositional, manufacturing, and commercial advantages

Natural tears | **Autologous Serum Tears (AST)** | **Human Platelet Lysate (HPL)**

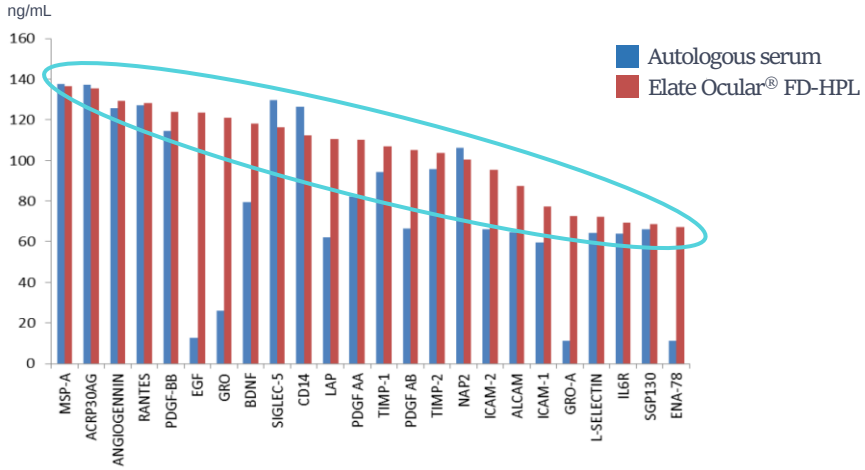
Composition of AST versus natural tears

Table 2 Comparison of the constituents of natural tears and peripheral blood serum

Parameter	Tears	Serum
pH	7.4	7.4
Osmolality	298	296
EGF (ng/ml)	0.2–3.0	0.5
TGF-β (ng/ml)	2–10	6–33
NGF (pg/ml)	468.3	54.0
IGF (ng/ml)	0.31	105
PDGF (ng/ml)	1.33	15.4
Albumin (mg/ml)	0.023	53
Substance P (pg/ml)	157	70.9
Vitamin A (mg/ml)	0.02	46
Lysozyme (mg/ml)	1.4	6
Surface IgA (µg/ml)	1,190	2
Fibronectin (µg/ml)	21	205
Lactoferrin (ng/ml)	1,650	266

- Autologous Serum Tears has been used as a treatment for DED since 1984
- Multiple published clinical studies have shown that ASTs are safe and efficacious
- ASTs have similar pH and osmolarity to natural tears
- ASTs have a higher concentration of growth factors compared with normal tear compositions

Superior composition of FD-HPL versus AST



- Elate Ocular® FD-HPL has a similar composition to AST, with enriched levels of EGF, PDGF, FGF, and other components associated with ocular surface regeneration
- FD-HPL has significant product advantages over AST:
  - ✓ Enriched levels of growth factors
  - ✓ Standardised composition with consistent quality
  - ✓ Convenient and non-invasive
  - ✓ More scalable
  - ✓ Potentially reimbursed

Source: Rauz (2009), Pan (2017), Zhang (2020), Emory University studies

Elate Ocular® clinical data

Demonstrated safety and efficacy in Phase 1/2 trial

- Study: "A Randomized Trial of Topical Fibrinogen-Depleted Human Platelet Lysate Treatment of Dry Eye Secondary to Chronic Graft-versus-Host Disease" (2020)
- CAM-101 drug (Elate Ocular®): two concentrations, 10% and 30%
- 64 adults, 9 sites in the United States
- 1:1:1 (vehicle : 10% : 30%) double-blinded randomisation
- Administration: 1 drop in both eyes, 4 times daily, for 42 days
- Primary endpoints: safety and tolerability
- Secondary endpoints: change in ocular signs and symptoms on Day 42

Safety: Overall Summary of Treatment-Emergent Adverse Events by Treatment Group

Patients With ≥ 1:	Vehicle Control (N = 22) n (%) m	FD hPL 10% (N = 20) n (%) m	FD hPL 30% (N = 22) n (%) m
AE	10 (45.5) 34	9 (45.0) 12	8 (36.4) 11
Treatment-related AEs	1 (4.5) 2	1 (5.0) 1	0
Ocular AE	7 (31.8) 19	4 (20.0) 6	2 (9.1) 2
Treatment-related ocular AEs	1 (4.5) 1	1 (5.0) 1	0
Serious AE	2 (9.1) 2	2 (10.0) 2	3 (13.6) 4
AEs leading to study withdrawal	1 (4.5) 6	1 (5.0) 1	0

AE = adverse event; m = number of events; N = number of patients in a specific group; n = number of patients with a particular AE; calculation of percentages based on N. Treatment-emergent AEs are defined as AEs that increased in severity or newly developed after first dosing.

Efficacy: Signs and Symptoms of Dry Eye: Comparison of Change from Baseline to Day 42

Parameter	Vehicle Control (N = 22)	FD hPL 30% (N = 22)	FD hPL 30%-Vehicle Control (Mean)	FD hPL 30%-Vehicle Control (2-sided p-value)
Burning/stinging	−6.39	−26.62	−20.23	0.045
Eye discomfort	2.77	−30.20	−32.97	<0.001
Eye dryness	−4.32	−25.92	−21.61	0.04
Photophobia	−11.20	−35.53	−24.33	0.025
Pain	−1.86	−16.97	−15.12	0.089
Grittiness	6.02	−14.06	−20.08	0.037
Tear film breakup time	−0.27	1.03	1.3	0.082
Investigator's global examination	4.52	3.66	−0.86	0.052
Ocular discomfort	−2.70	−20.73	−18.04	0.036
Fluorescein sodium staining score	−0.34	0.96	1.3	0.052

- Met primary endpoints of safety and tolerability at both low and high doses
- Met secondary symptoms endpoints at high dose, demonstrating efficacy
- Observed safety and efficacy profile supports transition to pivotal Phase 3 studies

Source: Sugar et al (2022) https://www.ophthalmologyscience.org/article/S2666-9145(22)00065-3/fulltext, clinicaltrials.gov NCT03414645

Elate Ocular® clinical development plan

Two registration-enabling* Phase 3 trials in DED

- Obtained Orphan Drug Designation (ODD) in Dry Eye Secondary to Chronic Graft-versus-Host Disease
- Obtained two Investigation New Drug (IND) application approvals from the FDA to initiate two Phase 3 trials
- Retained a Contract Development and Manufacturing Organisation (CDMO) to manufacture Elate Ocular®
- Retain a Contract Research Organisation (CRO) to administer Phase 3 clinical trials
- Apply for Regenerative Medicine Advanced Therapy (RMAT) designation with the FDA
- 2024: Initiation of two Phase 3 trials in DED**
- 2026: Readouts from two Phase 3 trials
- 2027: Submission of the Biologics License Application (BLA) with the FDA*

Legend
✓ Completed
✓ In process

Notes: * based on the FDA Guidance for Industry "Dry Eye: Developing Drugs for Treatment" https://www.fda.gov/media/144594/download
** subject to additional funding and manufacture of GMP Phase 3 Investigational Drug

Investment highlights

Unmet need	• Currently approved drugs provide only short-term symptom relief for dry eye disease patients with low tolerance and side effects. Elate Ocular® can become a differentiated therapeutic with superior DED symptom relief and sign improvement
Large addressable market	• DED is a highly prevalent indication, with 17M diagnosed adults in the USA alone (prevalence of 6.8%) • Over US$ 2BN in annual prescription drug expenditure in the USA. Expected to grow with new drug approvals
Differentiated platform technology	• A patent-protected platform technology to formulate allogeneic, fibrinogen-depleted human platelet lysate for therapeutic use • The technology can be leveraged in other disease areas – ophthalmology, orthopaedics, wound healing, dentistry, and others
Elate Ocular® late-stage asset	• The company obtained two IND Application approvals from the FDA to initiate registration-enabling Phase 3 trials in the USA
Supportive shareholders	• Key CMT shareholder(s) are ready to support further development of Elate Ocular®
Committed executive team	• Key executives, co-founders and advisors have been with CMT since its founding in 2013
Optionality in other clinical assets	• Cambium Bio will continue to pursue capital-efficient licensing options for Progenza and Sygenus cell therapy assets to drive incremental value for Cambium Bio shareholders

Acronyms and definitions

- AAO: American Academy of Ophthalmology
- AD-MSC: adipose-derived mesenchymal stem cells
- AE: adverse event
- Allogeneic: derived from a healthy donor (not patient)
- AST: autologous serum tears
- BLA: Biologics License Application
- CAM-101: Elate Ocular® investigational drug for dry eye disease
- Cambium Bio / Cambium: proforma combined company after the Cambium Medical Technologies, LLC acquisition by Regeneus Ltd
- CDMO: Contract Research and Development Organisation
- CMT: Cambium Medical Technologies, LLC
- CRO: Contract Research Organisation
- DED: dry eye disease, also known as Keratoconjunctivitis Sicca (KCS)
- EGF: epidermal growth factor
- FDA: Food and Drugs Administration
- FD-HPL: fibrinogen-depleted human platelet lysate
- GA: Georgia
- GMP: Good Manufacturing Practice
- HPL: human platelet lysate
- IND: Investigational New Drug
- MGD: Meibomian gland dysfunction
- oGvHD: ocular Graft versus Host Disease
- PDGF: platelet-derived growth factor
- QID: four times a day
- QOL: quality of life
- RGS: Regeneus Ltd
- RMAT: regenerative medicine advanced therapy
- TGFβ1: transforming growth factor β1
- UK: United Kingdom
- US: United States of America

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