ASX Announcement
28 April 2023

Regeneus agrees to merge with Cambium Medical Technologies

Introduction to Cambium Medical Technologies, LLC.

The Board of Regeneus Ltd (**Regeneus** or **Company**) is pleased to announce that it has signed a non-binding indicative offer letter to merge with Cambium Medical Technologies, LLC. (**CMT**).

CMT is a United States-based, clinical-stage regenerative medicine company developing a Phase 3-ready biologic therapeutic, *Elate Ocular*®, to treat dry eye disease (**DED**). CMT was founded in 2013 as a spin-off from Emory University, Georgia, USA, and has developed a proprietary process involving novel allogeneic human platelet lysate collected from healthy donors. CMT has previously raised seed and Series A funding from strategic investors and in 2020 completed a 64-patient Phase 1/2 trial with highly differentiated clinical readouts.

In addition, CMT has obtained two Investigational New Drug (**IND**) Application approvals from the U.S. Food and Drug Administration (**FDA**) to initiate two Phase 3 trials in chronic DED and DED in ocular Graft versus Host Disease (**oGvHD**). The planned Multi-Region Clinical Trial (**MRCT**) will include the USA and select Asia Pacific countries. CMT expects to submit a Biologics Licence Application (**BLA**) for marketing approval in FY 2026/27, subject to successful Phase 3 clinical trials and additional funding.

Unmet need for *Elate Ocular* drug

Dry eye disease (Keratoconjunctivitis Sicca) is a multifactorial disorder of tears and ocular surface. The underlying disease mechanism is a loss of tear film homeostasis - failure to produce high-quality or sufficient tears. The pathology may lead to visual disturbance, irritation, pain, corneal ulceration, conjunctival scarring, infection, and reduced quality of life.

The diagnosed patient population is over 17M adults in the USA alone, corresponding to a prevalence of 6.8%. The current market size for prescription drugs to treat DED in the USA is estimated to be in excess of US$2B and is expected to grow significantly as novel therapeutics, such as *Elate Ocular*, will become commercially available.

CMT's lead asset, *Elate Ocular*, is an allogeneic biologic drug comprised of fibrinogen-depleted human platelet lysate (**HPL**) pooled from multiple healthy donors. HPL, compositionally similar to native tears, will be positioned as an "off-the-shelf natural tear" to treat dry eye disease.

Approved competing prescription drugs in DED provide only short-term relief with low tolerance and significant side effects resulting in poor compliance and modest

resolution of patient symptoms. Alternatively, the composition of autologous serum tears (**AST**) is similar to *Elate Ocular*; however, AST are not scalable given the requirement to draw individual patients' blood regularly to formulate an autologous platelet-rich product. Therefore, *Elate Ocular* represents a potential off-the-shelf regenerative medicine approach for managing chronic DED and leverages clinical experience and familiarity with autologous serum tears.

Elate Ocular will become a lead clinical asset in the merged company. In addition, Regeneus will continue exploring the development and out-licensing opportunities for its existing Progenza™ and Sygenus regenerative medicine technology platforms.

Transaction rationale

Regeneus is excited to partner with CMT to accelerate the development of *Elate Ocular* by leveraging the promising asset and company characteristics:

- 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 potentially become a differentiated therapeutic with superior DED symptom relief and sign improvement.
- Large market opportunity. DED is a highly prevalent indication with 17M diagnosed adults in the USA alone.
- Differentiated technology. CMT holds a proprietary, patent-protected platform technology to formulate allogeneic, fibrinogen-depleted human platelet lysate for therapeutic use. The technology can be leveraged in various disease areas, such as ophthalmology, orthopaedics, wound healing, dentistry, and others.
- Promising first clinical asset. *Elate Ocular* has proven to be safe and well tolerated and demonstrated promising efficacy in the Phase 1/2 clinical trial to treat dry eye disease.
- Late-stage, Phase 3-ready opportunity. CMT has already obtained two IND Application approvals from the FDA to initiate Phase 3 trials in the USA.
- Attractive unit economics. With differentiated safety and efficacy profile and a highly scalable manufacturing process, *Elate Ocular* has the potential to become a lead value driver for the merged entity.
- Experienced management team. Highly experienced individuals will join the Regeneus team with ophthalmology and big pharma backgrounds.

Key merger transaction terms

Transaction structure. Regeneus will acquire 100% of CMT shares. Consideration for the acquisition of the shares will be the issue of new ordinary shares in Regeneus to existing CMT shareholders. Newly issued shares to CMT shareholders will represent 50% of Regeneus post-transaction issued share capital. As a result, the indicative post-merger number of outstanding shares will be:

Current shares outstanding	306,436,914
New shares to be issued to CMT shareholders	306,436,915
Post-merger shares outstanding	612,873,829

In addition, existing CMT shareholders will be entitled to a 5.5% revenue royalty from the existing version of *Elate Ocular* to treat dry eye disease.

Conditions precedent. The transaction is subject to the Regeneus shareholder approval under Listing Rule 7.1 to issue the consideration shares to the existing CMT shareholders. The transaction is also subject to the CMT shareholder approval.

Escrow. Key existing CMT shareholders and key Regeneus insiders will enter into voluntary escrow deeds in relation to Regeneus shares they hold, and will be restricted from selling Regeneus shares for 12 months after the transaction closing. It is expected that a total of c.60% of post-transaction shares will be escrowed.

Director appointment rights. It is expected that Prof. Graham Vesey will step down from the Regeneus Board of Directors on transaction closing and the existing CMT shareholders will have the right to nominate two new Board Directors to join the Regeneus Board on transaction closing.

Management team. A preliminary agreed senior management team will be as follows:

- Karolis Rosickas will continue to serve as a Chief Executive Officer after the transaction closes.
- Terence Walts, co-founder and Chief Executive Officer of CMT, will join as a Board Director and oversee the Company's US operations.
- Edmund K. Waller, MD, PhD from Emory University School of Medicine, scientific co-founder of CMT, will join as a Chief Scientific Officer of the Company.

Other select members of CMT senior management will join the merged entity.

Change of name. The merged company will change its name to "Cambium Bio Limited" (**Cambium Bio**) (subject to shareholder approval).

Future funding. Regeneus Board and principal CMT shareholders are considering future capital needs to support Cambium Bio future activities and working capital needs including Phase 3 trials for *Elate Ocular*. Any future capital raise could potentially include a participation by existing CMT shareholders and their associates.

Next steps

Regeneus has received an in principle confirmation from ASX that Listing Rules 11.1.1, 11.1.2 and 11.1.3 do not apply to the Proposed Transaction.

The Company will proceed to perform legal due diligence and negotiate definitive transaction agreements with CMT.

Regeneus expects to hold General Meeting to obtain shareholders' approvals and close the merger transaction in July 2023.

Regeneus CEO Karolis Rosickas commented: "Since our strategic discussions started in May 2022, we have been very excited about CMT's novel technology to address a significant unmet need in highly prevalent dry eye disease. Based on promising Phase 1/2 clinical data, *Elate Ocular* has potential to become a sustainable treatment solution for DED patients in the United States and Asia. With support from CMT's existing shareholders, we are thrilled to add *Elate Ocular* to our regenerative medicine

pipeline, run Phase 3 trials and commercialise or license the drug as a priority for the merged company."

Cambium Medical Technologies CEO Terence Walts commented: "We are enthusiastic about partnering with Regeneus and its management team to complete the development and obtain regulatory approvals for *Elate Ocular*. Regeneus' experience in developing and manufacturing advanced regenerative medicines will accelerate our development process and bring *Elate Ocular* to dry eye patients in an expedited manner. The partnership with Regeneus will also help the new Cambium Bio leverage *Elate Ocular* as a platform technology into other indications beyond dry eye disease. The merger will also be synergistic for CMT's current strategic partner (Zheng Yang Biomedical Technology Ltd, Taiwan), a worldwide leader in the rapidly expanding stem growth supplement market."

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About Regeneus

Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies. The regenerative therapies seek to address unmet medical needs in human health markets, focusing on osteoarthritis, neuropathic pain, and various skin conditions, with its platform technologies Progenza™ and Sygenus. Visit www.regeneus.com.au for more information.

About Cambium Medical Technologies LLC

Cambium Medical Technologies LLC is an Atlanta, Georgia based clinical-stage therapeutics company founded in 2013. It holds a worldwide license to a novel processed allogenic human platelets lysate technology (FD hPL trademarked Aurarix®). Cambium's mission is to improve patients' quality of life—from within. The Company's first FDA-approved therapeutic is targeted to be Elate Ocular®, a topical biologic eye drop for dry eye syndrome (keratoconjunctivitis sicca or KCS). The Company also believes its technology to be a platform technology, applicable in multiple therapeutic markets. Cambium's strategic partner Zheng Yang Biomedical Technology Ltd (ZYBT), Taipei, Taiwan has been exploiting Cambium's asset under a sub-license under the brand name UltraGRO into the worldwide stem cell growth supplement since 2015.

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Regeneus Ltd

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