

Teleconference at 11am (AEST) Thursday 23 July
Conference ID: 10008777. Pre-registration:
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Zelira enters into a commercial agreement to develop products targeting symptoms associated with Peripheral Arterial Disease and Diabetic Neuropathies

22 July 2020

- **Zelira and Cardiovascular Solutions of Central Mississippi (CVSCM) enter into a binding agreement to develop and commercialize products that target symptoms associated with Peripheral Arterial Disease and Diabetic Neuropathies**
- **Zelira will grant an exclusive license to CVSCM to manufacture, sell and otherwise commercialize Zelira's proprietary formulations in the USA**
- **Zelira will receive an upfront licensing fee and royalties on any commercialized products**
- **CVSCM will be responsible for all costs relating to the production, marketing, distribution and sale of the products in the USA**
- **This transaction expands and complements Zelira's strategic interests in cardiovascular indications while maintaining focus on the global launch of its proprietary Zenivol™ and HOPE™ products**

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF), a global leader in the development of clinically validated cannabis medicines, is pleased to announce it has entered into a binding product development agreement with USA based Cardiovascular Solutions of Central Mississippi (CVSM) to target symptoms associated with Peripheral Arterial Disease (PAD), associated ischemic neuropathies including Diabetic Neuropathies (DPN).

The products to be developed by Zelira under this agreement will be based on CBD and other cannabinoids derived from hemp. These products will provide novel and proprietary therapeutic options with

potentially improved efficacy and better tolerability to target a significant unmet need in addressing the epidemic of PAD and its debilitating complications.

Under the Agreement, Zelira will receive a non-refundable upfront licensing fee, with royalties to be received on the commercialized products that result from the Agreement. If successful, Zelira and CVSCM will look to rapidly commercialise these products in significant global markets with CVSCM retaining exclusive marketing rights to the USA market and Zelira retaining rights for all other markets, ex-USA. The efficacy of the products will be assessed by CVSCM in relevant patient groups in a real-world setting. All product development and commercialisation costs in the USA will be borne by CVSCM.

Zelira exclusively owns all products developed under this Agreement. The license granted by Zelira to CVSCM for the USA market, with regards to the commercialisation of products developed under this agreement, is for five years, in the first instance, renewable for additional five-year periods.

In America, diabetes is a public health crisis, costing \$326 billion dollars per year, according to the American Diabetes Association. By the year 2050, it is projected that 1 in 3 Americans will have diabetes according to a recent analysis from the Centers for Disease Control¹. Racial and ethnic minorities have the highest prevalence and the greatest burden of complications compared to Caucasian Americans. Two debilitating complications of diabetes are the development of atherosclerosis leading to PAD and DPN.

PAD is the leading cause of non-traumatic amputations. For the 30 million Americans who suffer from diabetes, 1 out of 3 over the age of 50 will develop PAD². Based on 2016 Global Burden of Disease, it is estimated that the global prevalence of peripheral arterial disease is 200 million. That represents 25.6% of global burden of cardiovascular disease. Neuropathic symptoms and impairment increase with disease severity of PAD and diabetes – both areas with documented unmet therapeutic needs.

Associated diabetic neuropathy can also have substantial consequences for patients. Diabetic neuropathy is the most common complication associated with diabetes, which has a lifetime prevalence of 50-70%. DPN is also a leading cause of disability due to foot ulcerations, gait disturbances; fall risks and can potentially lead to infection and limb amputation. Both amputations and chronic neuropathic pain lead to poor quality of life, loss of productivity to society, high mortality rates comparable to cancer, significant economic burden to health care systems, and functional limitations caused by symptoms of their underlying diseases. A major complication associated with amputation is that 95% of amputees suffer from chronic pain syndromes.

According to the Centers for Disease Control and Prevention (CDC), type 2 Diabetes is responsible for about 90% of diabetes cases due to insulin resistance. High blood sugars damage the vessel walls (capillaries) decreasing the ability to supply nutrients and oxygen to the nerves. When the nerves are damaged, it interferes with the ability to send appropriate signals to the body hence producing wide-

¹ National Diabetes Statistics Report, 2017. CDC website. [cdc.gov/diabetes/pdfs/data/statistics/national-diabetesstatistics-report.pdf](https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetesstatistics-report.pdf). Published and accessed July 18, 2017

² https://www.nhlbi.nih.gov/health/educational/pad/docs/pad_extfctshg_general_508.pdf

ranging symptoms from numbness to constant disabling pain. These patients suffer in isolation, isolated by the physical and financial pain that this silent disease inflicts on them and their families.

Dr. Foluso Fakorede, CEO of CVSCM said “We are delighted to partner with Zelira, one of the world’s leading clinical medical cannabis companies, to pursue new and effective treatment options for PAD and Diabetes associated peripheral neuropathies. There has been significant progress in the understanding of the molecular mechanisms of cannabinoid action that target multiple medical conditions. A number of these cannabinoid-based medicines are approved by the U.S Food and Drug Administration’s (FDA) on the basis of scientific evidence. Our mission is to promote the prevention and treatment of cardiovascular disease in all patients and to achieve health equality for marginalized communities through implementation of applications that address unmet needs.

Dr. Oludare Odumosu, CEO & Managing Director USA for Zelira said “Our partnership with CVSCM is in line with our mission to target indications where cannabinoid-based medicines can be used as safe, effective and accessible options. This collaboration represents the first of its kind in this field and allows us to focus on the impact of PAD on quality of life for patients. Dr. Fakorede and the CVSCM team have led the way in reducing rates of amputations in the Mississippi area through intervention and education on the risks and burden of PAD. Zelira is proud to bring our scientific product development expertise to this unmet need and expands our reach into new indications and markets.

DISCLOSURES:

- The Company cannot, at this stage, fully quantify the impact of the contract will have on the price of its securities.
- The Company does not expect, that by itself, the upfront licence fee element of the Agreement will have a material impact on its operations for the financial year ended 30 June 2021, but the Agreement has the potential to create a future long term revenue stream for the Company in addition to its HOPE™ and Zenivol™ products.
- As is usual in agreements, the Agreement is terminable mutually or when one party fails to perform. However, in all instances, the Company continues to own 100% of its intellectual property and the products it develops under this Agreement and keep the non-refundable upfront fees it receives.
- This transaction continues the evolution of the Company from a non-revenue generating company (the Company had no revenue as of 1 January 2020) towards a revenue generating commercial company.

This announcement has been approved and authorised for release by the board of Zelira Therapeutics Limited.

Oludare Odumosu, MPH, Ph.D.
Managing Director USA

About Zelira Therapeutics (www.zeliratx.com)

Zelira Therapeutics Ltd is a leading global therapeutic medical cannabis company with access to the world's largest and fastest growing cannabis markets. Zelira owns a portfolio of proprietary revenue generating products and a pipeline of candidates undergoing clinical development that are positioned to enter global markets from 2020. The company is focused on developing branded cannabis products for the treatment of a variety of medical conditions.

The Company is undertaking product development programs targeting specific conditions (e.g. HOPE™) and human clinical trial programs focused on insomnia, autism and opioid reduction in patients with chronic non-cancer pain.

The Company conducts this work in partnership with world-leading researchers and organizations including Complutense University in Madrid, Spain; Curtin University in Perth, Western Australia; the Telethon Kids Institute in Perth; the University of Western Australia, in Perth; St. Vincent's Hospital in Melbourne, Australia; and the Children's Hospital of Philadelphia (CHOP) in the United States.

The Company has developed two proprietary formulations (HOPE™) already launched and generating revenues in Pennsylvania, has laboratory capabilities to develop formulations in Pennsylvania and Louisiana with ability to conduct clinical trials and is establishing a national footprint across the US for the licensing of its products.

About Cardiovascular Solutions of Central Mississippi About CVSCM (PADadvocate.com)

Cardiovascular Solutions of Central Mississippi is a center of excellence in the heart of the Mississippi Delta founded in 2015 to bridge the gap in cardiovascular health disparities that have long plagued the region. It became the first cardiovascular minority physician-led comprehensive outpatient-based clinic and procedural center in the state of Mississippi. Dr. Fakorede assembled a great team to help accomplish a herculean mission of having treated over 10,000 patients and aiming to reduce geographic disparities in access to care by putting on an apron of humility - to serve others with dignity and quality care. He and his teammates made the invisible people with PAD visible and worked on behalf of a forgotten region to bridge the cardiovascular health equality gap, by encouraging preventative mindset in community outreach programs.

Amputations and complications from diabetes are at pandemic rates in the Mississippi Delta. Dr. Fakorede has been on the forefront of bringing awareness to PAD and health disparity of minorities and has worked tirelessly on policy and multiple national advisory boards to bring attention to this epidemic rate of non-traumatic amputations

CVSCM founding clinical member - Dr. Fakorede, Amy Harlow RN, BSN, along with other collaborators, published The Mississippi Delta Miracle: Angiographic Screening Yields Dramatic Reduction in Amputations in January 2019 edition of Cathlab Digest. The article successfully highlights the path taken by the practice to reduce amputation rates by 88% over 4-year span, and in the process securing patient access to high-quality and cost-effective interventional treatment across the region. The CVSCM daily efforts in their fight against health inequities in the PAD space has been printed in multiple Op-ed publications and recently, the ProPublica publication of The Black American Amputation Epidemic. The awareness campaign has led to over 150 million people reached, NBC nightly news appearance with Lester Holt, and reprinted in multiple respected journals. The CVSCM team has become the gold standard for PAD advocacy with a purpose driven mantra to impact the lives of all underserved communities by demanding a clarion call to action on behalf of the voiceless while seeking disruptive therapies that will ultimately bridge treatment gaps in addressing health care inequities.

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Conference call details

Time: 11:00 (AEST) Thursday 23

July

Conference ID: 10008777

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