

Zelira Therapeutics Ltd

08:40 01 Sep 2021

Zelira Therapeutics' commercialisation program to see launch of suite of new cannabinoid-based products over FY22

Zelira Therapeutics Ltd (ASX:ZLD, OTCQB:ZLDAF) continues to focus on the expansion of commercialisation activities and revenue generation from its new clinically tested products, with the strategy expected to lead to the launch of a suite of new cannabinoid-based products over FY22.

Commercialisation plans are focused on generating revenues from the multiple products it has launched into the Australian and US markets.

The company plans to continue to launch new product lines while expanding into new geographies such as the UK and Germany.

Commercialisation milestones

During FY21, the company significantly progressed its growth strategy, achieving key milestones set by the new leadership team.

It also brought forward future development and commercialisation milestones following successful capital raisings.

They include:

? Cardiovascular Solutions of Central Mississippi (CVSCM) deal

Zelira entered into a binding product development agreement with US-based CVSCM to develop products that target symptoms associated with Peripheral Arterial Disease (PAD) - the leading cause of non-traumatic amputations in the US.

? Phase 1 dose-escalation study in chronic pain

The Phase 1 dose-escalation trial in chronic pain patients on long-term high-dose opioid treatment met its primary and secondary endpoints for safety and efficacy. These trial results informed the design of the trial being undertaken with Levin Health targeting retired athletes with chronic pain and also accelerate plans to expand Zelira's portfolio of chronic pain products, supported by clinical trial data.

? HOPE™ launched in Louisiana

Zelira launched HOPE™ 1 & 2 in Louisiana, USA, through licensee Advanced Biomedics and hopes to repeat the success of HOPE in Pennsylvania, where it has established itself as one of the top-selling medicinal cannabis products.

? Zenivol™ launched in Australia

Price: 0.037

Market Cap: \$44.04 m

1 Year Share Price Graph



Share Information

Code: ZLD

Listing: ASX

52 week High Low
0.14 0.036

Sector: Cannabis

Website: www.zeldatherapeutics.com

Company Synopsis:

Zelira Therapeutics Ltd (ASX:ZLD) is a leading global medical cannabis company with access to the world's largest and fastest-growing cannabis markets. The company owns a portfolio of proprietary revenue-generating products and has a pipeline of candidates undergoing clinical development that are positioned to enter global markets soon.

action@proactiveinvestors.com.au

Following its successful clinical trial, Zenivol™, Zelira's proprietary cannabinoid medicine, was approved by the Therapeutics Goods Administration (TGA) for prescription to patients in Australia via its Special Access Scheme.

? Real-world data agreement for insomnia drug Zenivol

Zelira entered into an agreement with Emyria Ltd (ASX:EMD) (formerly Emerald Clinics) to collect data from patients treated with Zenivol in Emyria's network of specialist medical clinics.

Real-world data collected from patients will complement the existing clinical data-pack for Zenivol and will be used to inform further clinical development and, evaluation of the path to product registration.

? HOPE autism products launched in Australia

Zelira's proprietary cannabinoid medicines HOPE 1™ and HOPE 2™ were made available for prescription to patients in Australia through the TGA Special Access Scheme and via authorised prescribers.

? Emyria partnership for autism observational trial for HOPE products

Zelira partnered with Emyria to undertake an observational trial in patients diagnosed with ASD treated with the HOPE range of products - one of the largest medicinal cannabis studies ever undertaken involving a specific range of products in patients diagnosed with ASD.

? SprinJene® partnership

Zelira launched its proprietary CBD toothpaste in the US in partnership with SprinJene®, a leader in natural oral care products.

SprinJene was launched in the UK in June 2021, and discussions are ongoing to access SprinJene's global distribution networks in France, Russia, Singapore, Ukraine, China, Morocco, UAE, Saudi Arabia and Sudan Shoprite.

? Transfer of leadership

As part of a strategic consolidation of its operations, leadership was transferred to the US-based team and Dr Oludare Odumosu assumed the role of global managing director, allowing Zelira to optimise its exposure to the rapidly expanding US cannabis sector while also continuing to grow its revenues in ex-US markets.

? National Cannabis Round (NCR) table

Zelira was appointed to NCR's Board of Directors and is being represented by managing director Dr Oludare Odumosu.

A non-partisan advocacy group focused on federal cannabis reform in the US, NCR is seeking to balance respect for state-legal cannabis programs with common-sense federal regulation in the US, to realise the full potential of the legal cannabis industry.

? HOPE range of autism spectrum disorder products in Washington DC

Since May 2021, Alternative Solutions LLC, a licensed grower, manufacturer, and distributor of medical cannabis products, has been distributing Zelira's HOPE range of products in the District of Columbia (Washington DC).

Washington DC has reciprocity with 32 other States in the US with approved medical cannabis programs and as such, the market for the HOPE range is far larger than just the population of the District of Columbia.

? CBD toothpaste launch in the UK

It signed a five-year exclusive distribution agreement with Health House International Limited (ASX:HHI) in the UK, which further expands the availability of Zelira's SprinjeneCBD toothpaste brand beyond the US.

The UK market provides significant growth opportunities for Zelira's clinically validated, hemp-derived oral care products.

? Levin health licensing and management agreement

It licensed a proprietary cannabinoid formulation to Levin Health Limited to undertake a clinical trial to test the efficacy of the formulation in treating sports-related chronic pain experienced by retired professional and amateur athletes.

? Significant uptake of CBD into the brain

Its funded team of researchers at Curtin University (Australia) developed a new technology to improve the delivery of cannabidiol-based drugs into the brains of mice at a rate up to 40-times more than has previously been delivered. The technology has the potential for cannabinoid-based therapies to treat neurological disorders such as Alzheimer's disease, multiple sclerosis, and traumatic brain injury.

The research was published in the leading peer-reviewed open access scientific journal PLOS ONE.

? Zenivol results published in SLEEP

The clinical trial results of Zenivol were published in the prestigious peer-reviewed journal SLEEP® while the trial results of the University of Western Australia's investigational team that undertook the double-blind, placebo-controlled, cross-over trial of Zelira's ZTL-101 (on market as Zenivol) in chronic insomnia patients were published in the Sleep Research Society's peer-reviewed journal for all sleep-related conditions.

IRB approval

Zelira received IRB approval for its 12-week observational clinical study to evaluate the efficacy, safety and tolerability of its proprietary, patent-protected product against a multi-billion-dollar Big Pharmaceutical company drug.

Zelira had successfully navigated a unique regulatory path for this trial and looks forward to the results of the study, which are anticipated in the first half of 2022.

Strongly supported fundraising

The company significantly strengthened its balance sheet In August 2020 with a strongly supported and oversubscribed A\$8.75 million placement before costs at an offer price of \$0.05 per share.

A further A\$2 million placement was made to Thorney Investment Group in September 2020, which increased their interest to become a substantial shareholder with a 5.2% stake in the company.

Subject to shareholder approval at Zelira's Annual General Meeting in November 2021, the company will issue Thorney a one-for-one free attaching unquoted option, exercisable at A\$0.07 and expiring two years from the date of issue.

The capital raised has enabled Zelira to accelerate commercialisation, launch five products into global markets, and leverage its unique 'Launch, Learn and Develop' model to launch products, generate revenues, and progress the development of clinically validated medicines.

Healthy working capital ratio

The net assets of the consolidated group increased by A\$3,282,714 from A\$34,546,925 at June 30, 2020, to A\$37,829,639 at June 30, 2021,

The group maintained a healthy working capital ratio, with working capital rising from A\$1,162,501 as at June 30, 2020, to A\$5,014,801 at June 30, 2021.

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +61 (0)2 9280 0700 action@proactiveinvestors.com.au

No investment advice

Proactive Investors Australia Pty Ltd ACN 132 787 654 (the Company, we or us) provides you with access to the content set out above, including any news, quotes, information, data, text, reports, ratings, opinions, images, photos, graphics, graphs, charts, animations and video (Content) and this website (the Site) on the terms set out in this disclaimer, together with all other terms and conditions, disclaimers and other notices displayed elsewhere on this Site.

It is important for you to know that:

- (a) none of the Content is, or is intended to be, general or personal advice
- (b) the principal purpose of the Content is to provide factual information only and to comment on news;
- (c) the Content does not contain or imply any recommendation or opinion intended to influence your financial decisions, including in respect of any particular security, portfolio of securities, transaction or investment strategy, and must not be relied upon by you as such;
- (d) in providing you with the Content, we have not considered your objectives, financial situation or needs; and
- (e) you should make your own enquiries and obtain your own independent advice prior to making any financial decisions.

The Content contains data (including but not limited to prices, statistics and calculated information) obtained from a variety of third party sources (Third Party Data). The Company does not make any representation or warranty that any of the Content, including the Third Party Data, will be reliable, accurate or complete. The Company disclaims all responsibility and liability arising in any way from any errors or omissions in the Content, including the Third Party Data, including any loss you may incur in connection with any action or decision made by you in reliance upon the Content or Third Party Data.

In certain circumstances the Company, its related bodies corporate, or their affiliates, may have received, or be entitled to receive, financial or other consideration in connection with providing information about certain entities on the Site, which may include the above Content.