

September 30, 2020



# Emerald Bioscience Provides Corporate Update

**Renewed team and capital focused on advancing lead compound for glaucoma into human studies**

**Ongoing development of lead compound, THCVHS, includes near-term preclinical assessments of neuroprotection and comparison with leading glaucoma treatments**

**Preclinical studies of CBDVHS will examine its utility for ocular, neurological, pain and addiction disorders**

San Diego, Calif., Sept. 30, 2020 (GLOBE NEWSWIRE) -- Emerald Bioscience, Inc. (OTCQB: EMBI) ("Emerald" or the "Company"), a preclinical-stage biopharmaceutical company focused on developing proprietary first-in-class molecules with strong clinical and commercial differentiation, provides an update on progress across its product pipeline, including adjusted clinical milestones.

"Emerald's restructured management team completed a review of the company's accomplishments and necessary next steps. After updating our development plan and recently strengthening our capital position, our board of directors yesterday approved this proactive and well-considered action plan. Today we begin to deploy this renewed plan to advance, in particular, our lead product candidate toward our first human study next year," said Punit Dhillon, Emerald's CEO and Chairman. "COVID-19 has adversely impacted our previously stated timelines and progress, but it has in no way diminished the significant therapeutic potential of our novel molecules. Our drug candidate for glaucoma has the potential to deliver important signals of efficacy in the very first human study we conduct. It is a tremendous advantage to have a drug-disease combination able to produce a possibly significant and meaningful data outcome in a short and resource-effective manner. Our team is excited about our immediate path to completing the final preclinical steps, which will enable the initiation of our planned human study of THCVHS in Australia.

"Our revitalized plan also includes the advancement of our earlier-stage CBDVHS program. THCVHS and CBDVHS both have broad potential applications in humans across ocular, neurological, infectious, and other diseases. We are laser-focused on getting THCVHS into the clinic but will prudently advance our preclinical plan to develop our CBDVHS molecule as well. We look forward to providing updates as we advance the Company's proprietary synthetic compounds toward the clinic in 2021."

## Financing Update

- The company recently raised \$7.0 million in a registered offering. Proceeds will be

used primarily for preclinical and clinical development of THCVHS and CBDVHS and general corporate purposes, including working capital.

## **Corporate Update**

- The Company restructured its management team, including:
  - The board of directors appointed biotech executive Punit Dhillon as Chief Executive Officer following its acceptance of Dr. Brian Murphy's resignation. Mr. Dhillon continues to serve as Chairman of the Board.
  - Tu Diep, MSc., Senior Vice President of Development, brings more than 15 years of clinical operations, CMC, regulatory affairs, and business development experience, further strengthening the clinical development team.
  - Dr. Dennis Kim continues to serve as Chief Medical Officer, spearheading the launch of clinical trials in glaucoma.
- The Company announced the appointment to the board of a new independent director, Margaret R. Dalesandro, Ph.D., who brings more than 25 years of drug development experience in pharmaceutical, biotechnology and diagnostics.
- The Company expanded its global, exclusive patent rights that cover THCVHS and CBDVHS, including 22 granted patents that cover THCVHS and 5 granted patents and 9 pending patent applications that cover CBDVHS.
- The Company has exclusive, worldwide, "all fields" license agreements with the University of Mississippi, which rights include all uses of THCVHS and CBDVHS molecules and employing any formulation via all routes of administration for both human and veterinary uses.
- The Company is considering an appropriate path to up-list to a major stock exchange in order to enable a broader spectrum of the investment market to participate in Emerald's stock and also to enhance the recognition and profile of the company.

## **Clinical Development Update: THCVHS, a prodrug of THC for the treatment of glaucoma and potentially other ocular diseases, advancing on a complete, prioritized plan**

- In preclinical studies, THCVHS demonstrated greater ability to lower intra-ocular pressure (IOP), with comparable durability during the study period, versus latanoprost and timolol, medications that comprise more than 90% of the current glaucoma market.
- THCVHS showed the potential to be dosed once daily, enhancing the drug's possible competitive profile in the marketplace. Using a new nanoemulsion eyedrop formulation, the compound demonstrated sustained lowering of IOP. The active part of the prodrug, THC, demonstrated direct lowering of IOP as well as significant antifibrotic, anti-inflammatory, and anti-neovascularization effects, suggesting multiple potential mechanisms of action in lowering IOP and potential neuroprotection of retinal ganglion cells (neurons that are susceptible to early death in glaucoma which leads to blindness).
- The Company plans to initiate additional preclinical mechanistic and pharmacologic studies to further its understanding of THCVHS. These studies will compare THCVHS' effect on IOP versus netarsudil and latanoprost and evaluate potential additive and/or synergistic effects of THCVHS with these agents. The Company also plans to further study the neuroprotective effects of THCVHS.
- The company plans to initiate a repeated dosing toxicology study of THCVHS,

conducted to Good Laboratory Practice (GLP) standards, to satisfy the FDA's IND requirement.

- The Company plans to initiate its first in-human clinical study for the treatment of glaucoma in Q32021 with data anticipated in early 2022. The study will consist of a single ascending dose (SAD) arm in healthy volunteers, followed by a multiple ascending dose (MAD) arm in healthy volunteers, and will also assess subjects with glaucoma and/or elevated IOP.

### **Research & Development Update: CBDVHS, an analog of CBD with potential for multiple therapeutic indications**

- Early preclinical data supports the potential for multiple therapeutic applications for Emerald's proprietary molecule, CBDVHS, in particular ocular, neurological and pain indications.
- In preclinical ocular studies, CBDVHS achieved key results:
  - Entered multiple compartments of the eye and may beneficially impact disease in the anterior compartment (uveitis and dry eye) and posterior compartment (retinopathies, macular degeneration).
  - Significantly lowered biomarkers of inflammation and fibrosis.
- In preclinical neurological studies, CBDVHS achieved key results:
  - Displayed greater anti-seizure activity in an in vitro epilepsy model compared to CBD over a 7-day period.
  - Planned animal studies will assess potency versus bioavailability of CBDVHS and CBD in a murine epilepsy model.
- In preclinical pain and addiction studies, CBDVHS:
  - Demonstrated an analgesic effect comparable to morphine in chemotherapy-induced peripheral neuropathy.
  - Demonstrated an anti-addictive profile, making the molecule a potentially safer alternative to opioids for pain.
- Additional preclinical studies are underway to determine initial disease targets, additional formulations, and routes of administrations for non-ocular indications, as well as to assess the impact of CBDVHS on various organ systems, including the brain and liver.
- Pharmacokinetic studies in preclinical species are planned, which will enable performance of regulated safety studies required to initiate in-human trials.

### **About Emerald Bioscience, Inc.**

Emerald Bioscience Inc. is a biopharmaceutical company focused on the discovery and development of first-in-class molecules with strong clinical and commercial differentiation for conditions with significant, global, unmet medical needs. With proprietary technology licensed from the University of Mississippi, the Company is developing novel ways to deliver its synthetic cannabinoid-derived molecules for specific indications with the aim of optimizing therapeutic benefit. The Company's aim is to clinically develop multiple proprietary compounds alone or in combination with corporate partners. For more information, visit [www.emeraldbio.life](http://www.emeraldbio.life)

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## **FORWARD LOOKING STATEMENTS**

This press release contains forward-looking statements, including statements regarding our product development, business strategy, relocation of corporate headquarters, timing of clinical trials and commercialization of cannabinoid-based therapeutics. Such statements and other statements in this press release that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition and stock price could be materially negatively affected. In some cases, forward-looking statements can be identified by terminology including "anticipated," "contemplates," "goal," "focus," "aims," "intends," "believes," "can," "could," "challenge," "predictable," "will," "would," "may" or the negative of these terms or other comparable terminology. We operate in a rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements the Emerald may make. Risks and uncertainties that may cause actual results to differ materially include, among others, our capital resources, uncertainty regarding the results of future testing and development efforts and other risks that are described in the Risk Factors section of Emerald's most recent annual or quarterly report filed with the Securities and Exchange Commission. Except as expressly required by law, Emerald disclaims any intent or obligation to update these forward-looking statements.



Source: Emerald Bioscience, Inc.