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# Lexaria Bioscience Advances 2021 Strategic Initiatives

## *Lexaria Focusing on Four Core Business Segments:*

- *Heart disease including hypertension*
- *Reduced-risk non combusted nicotine*
- *Improved antiviral drug delivery*
- *CBD from hemp*

**KELOWNA, BC / ACCESSWIRE / November 5, 2020** /Lexaria Bioscience Corp. (OTCQX:LXRP) (CSE:LXX) (the "Company" or "Lexaria"), a global innovator in oral drug delivery platforms, is pleased to outline its planned strategic initiatives for 2021 with a sharply enhanced focus on solutions related to the regulated pharmaceutical and medical market segments where it believes its patented technology will offer the highest value and utility.

Lexaria will concentrate its patented DehydraTECH drug delivery technology on four core areas of business with out-licensing strategies to existing drug manufacturers:

- Heart disease including hypertension utilizing CBD;
- Reduced-risk methods of delivering non-combusted nicotine;
- Improving antiviral drug delivery for applications that include Covid-19, influenza, herpes, hepatitis and AIDS; and
- Hemp-based CBD business-to-business ("B2B") applications for non-pharmaceutical consumer and therapeutic or medicinal products and prospective pharmaceutical indications beyond hypertension.

## **HEART DISEASE AND HYPERTENSION**

The current global market size for drugs used to treat various heart diseases is \$47.29 billion<sup>(1)</sup>, and anticoagulants, antihypertensive, and antihyperlipidemic drugs comprise roughly 90% of these. Broad trends including aging populations and obesity are expected to contribute to growth in demand for heart disease-related drugs, where demand is expected to reach \$63.96 billion by 2026 <sup>(2)</sup>.

Cardiovascular disease caused 840,678 deaths in the US during 2016 and more than one-third of all Americans suffer from some form of cardiovascular disease. The three leading companies in the cardiovascular drug market are thought to be Bristol-Myers Squibb; Pfizer, and Janssen Pharmaceuticals.

Lexaria has already demonstrated in a pilot human clinical study, published in a peer-reviewed medical journal in 2019, that its DehydraTECH processed cannabidiol (CBD) was associated with a statistically significant slight decrease in human blood pressure, theorized to have occurred as a result of the known vasodilatory potential of CBD. As a complex fat-soluble molecule, generic CBD is known to have poor absorption characteristics, such that typically only about 6% of what is orally ingested actually finds its way into blood circulation. Lexaria's technology has shown an ability to increase this absorption into the blood circulation by between 100% to 500%.

Lexaria is expecting to commence a second exploratory human clinical study intended to corroborate and expand on the findings of the original pilot study. Clinical test articles have been manufactured and are ready for shipment to the clinical site pending regulatory clearance for importation purposes. If this study is successful, Lexaria will then begin systematic outreach to some of the world's participants in the cardiovascular disease drug industry to introduce DehydraTECH's enhancement technology.

Lexaria's DehydraTECH is patent granted in the European Union and Australia for treatment of heart disease utilizing CBD, and the Company continues to seek international expansion of its patent protection utilizing CBD throughout the world.

## **REDUCED RISK NON-COMBUSTED NICOTINE**

Through a series of animal and human volunteer studies, Lexaria has repeatedly evidenced that its DehydraTECH technology significantly increases both the speed and ability of orally administered nicotine to reach the blood circulatory system and to cross the blood brain barrier. Lexaria's own limited human testing utilizing its most recent 2020 powdered nicotine formulations appear to demonstrate nicotine absorption and onset of nicotine effectiveness in as little as 1.5-4 minutes after an oral dose.

The global tobacco market is expected to be valued at \$1.08 trillion by 2027<sup>(3)</sup>, making it one of the largest industries in the world. Combustible tobacco demand is shrinking by 2% per year, while demand for non-combusted alternative is growing at approximately 10% per year. The nicotine replacement therapy market size in 2019 was \$2.55 billion and is expected to reach \$3.54 billion by 2027<sup>(4)</sup>.

There are an increasing number of alternatives to combustible tobacco experiencing dramatic growth in demand as consumers search for reduced risk method nicotine options, including the e-cig market, currently valued at \$12.41 billion and projected to reach \$68.48 billion by 2027; as well as the nicotine oral pouch market, currently valued at \$2.37 billion and expected to reach \$32.77 billion by 2026.<sup>(5)</sup> Products in the oral pouch category were the first nicotine products in the history of the Food and Drug Administration (the "FDA") to be authorized through the Modified Risk Tobacco Product pathway approved for claims of a lower risk of mouth cancer, stroke, lung disease, heart disease, emphysema and chronic bronchitis than cigarettes.

Lexaria has been successful in developing relationships with two of the world's largest tobacco companies, Altria Ventures Inc and British American Tobacco. Lexaria has also engaged in business dialogue with other tobacco and nicotine companies located in various parts of the world. Lexaria's DehydraTECH is patent granted in the USA, the European

Union and Australia for oral delivery of nicotine.

## **ANTIVIRAL DRUGS**

Early in 2020 Lexaria initiated early-stage research into the prospective applicability of DehydraTECH technology related to improved delivery characteristics of a number of existing antiviral drugs. Because DehydraTECH has repeatedly evidenced an ability to more efficiently deliver lipophilic CBD and nicotine, Lexaria first began postulating in 2019 that the technology may have applicability for a range of applications in the traditional pharmaceutical sector.

Viral-caused diseases such as HIV, hepatitis, influenza, and coronavirus remain common and at times reach pandemic proportions. Hepatitis caused 1.3 million deaths in 2015<sup>(6)</sup>; influenza had 13 million cases reported in 2019 in the US alone; Covid-19 has infected over 48 million people worldwide during 2020 and is currently infecting more than one-half million people per day. Additionally, there are currently 37.9 million people worldwide infected with HIV/AIDS.

Vaccines help prevent the transmission of, - but do not treat - viral diseases and generally have effectiveness rates of between 50% and 80%. Antiviral drugs will always be needed to treat people who become infected and are at risk of serious health consequences with viral diseases, and in many cases are the difference between life and death. The antiviral drug market is currently \$52.2 billion and expected to grow to \$75.3 billion by 2027<sup>(7)</sup>. Some of the largest companies competing in the antiviral drug market include Abbvie; Gilead Sciences; GlaxoSmithKline; and Merck and Co.

Many antiviral drugs are currently administered via injection, a process usually requiring a health care professional that introduces expense and complication for mass dosing. Lexaria believes it is possible that DehydraTECH could improve delivery performance such that some of these drugs could be dosed via oral tablet or capsule which is less expensive and makes it easier and less expensive to treat more patients in less time. To date, DehydraTECH has been clinically studied only with CBD and nicotine as potential active pharmaceutical ingredients ("APIs") and the results of these studies may not be predictive of the results of subsequent trials incorporating other APIs. Therefore, we are not certain if DehydraTECH will improve delivery of or be compatible with existing or future antiviral therapies, including those used to treat COVID-19.

Lexaria has designed a human clinical pilot study to test the effectiveness of DehydraTECH in delivering higher proportions of antiviral drug into the human blood stream, versus otherwise identical non DehydraTECH-processed antiviral drugs. Hospital ethics board approval has been received to conduct this study, conditional on further federal government approval which the Company is evaluating the necessary steps to pursue.

Lexaria has significantly advanced an early-stage R&D-focused rodent based pharmacokinetic ("PK") study to test DehydraTECH's ability to deliver a higher proportion of existing antiviral drugs into animal blood circulation with animal dosing already completed and data analyses expected to commence shortly. For both the human study and the animal study, two drugs have been selected that are representative of two leading possible classes of drugs currently being examined by others as potential treatments for COVID-19. PK study outcomes are almost always needed as part of a data package to present to established

drug companies in hopes of future collaboration. Lexaria's technology is currently patent pending for use with antiviral drugs.

## **CBD FROM HEMP**

Lexaria has previously reported growth in its CBD B2B processing division of more than 500% this year between its fiscal 4<sup>th</sup> quarter ended August 31, 2020 and fiscal 1<sup>st</sup> quarter ending November 30, 2020. Third party corporate demand for DehydraTECH to improve the delivery and performance characteristics of CBD has exceeded expectations. Lexaria has previously sold direct-to-consumer CBD-related products of only thousands of servings per quarter. Demand from corporate purchasers for DehydraTECH-enabled CBD powders, in contrast, is expected to exceed 8 million servings during the current quarter and is expected to continue to rise into 2021. As a result, Lexaria's hemp business division intends to discontinue the sale of its direct-to-consumer CBD products and will focus on the high-growth B2B CBD powder processing segment, and on continued out-licensing of its intellectual property to generate royalty revenues from third-party companies seeking to improve their consumer's experiences by utilizing Lexaria's technology for their hemp derived CBD product offerings.

The global CBD market was estimated at \$4.6 billion in 2018, growing rapidly and expected to reach \$23.6 billion in 2025<sup>(8)</sup>. Although the CBD market size is smaller than the other opportunities under pursuit by the Company, the Company's technology was first developed to enhance the delivery of CBD and the Company has an established business presence within the sector that is experiencing revenue growth.

Many studies are underway around the world investigating CBD for potential treatment of several medical conditions including opioid and other substance abuse, anxiety and more. In harmony with the increased scientific investigation, CBD is also gaining recognition as a regulated drug with significant medical potential. For example, Epidiolex generated \$296 million in revenue<sup>(9)</sup> for its owner, GW Pharmaceuticals, during 2019. Epidiolex is regulated by the FDA as a treatment for certain forms of childhood epilepsy, a central nervous system disorder.

Lexaria's DehydraTECH is patent granted in the European Union and Australia for treatment of a range of central nervous system disorders using CBD and, as previously noted, Lexaria continues to seek international expansion of its patent protection utilizing CBD.

Chris Bunka, CEO, is responsible for the accuracy of this news. The Company is not making any express or implied claims at this time that its products or technology have the ability to eliminate, cure or contain Covid-19 (or SARS-2 Coronavirus) nor any other therapeutic drug indication.

## **About Lexaria**

Lexaria Bioscience Corp.'s (OTCQX: LXRP, CSE: LXX) proprietary drug delivery technology, DehydraTECH™, improves the way active pharmaceutical ingredients (APIs) enter the bloodstream by promoting healthier oral ingestion methods and increasing the effectiveness of fat-soluble active molecules, thereby lowering overall dosing. The Company's technology can be applied to many different ingestible product formats, including foods, beverages, oral suspensions, tablets, and capsules. DehydraTECH increases bio-absorption by up to 5-10x,

reduces time of onset from 1 - 2 hours to minutes, and masks unwanted tastes for orally administered bioactive molecules, including anti-virals, cannabinoids, vitamins, non-steroidal anti-inflammatory drugs (NSAIDs), nicotine, and other molecules. Lexaria has licensed DehydraTECH to multiple companies including a world-leading tobacco producer for the development of smokeless, oral-based nicotine products and for use in industries that produce cannabinoid beverages, edibles, and oral products. Lexaria operates a licensed in-house research laboratory and holds a robust intellectual property portfolio with 18 patents granted and approximately 60 patents pending worldwide. For more information, please visit [www.lexariabioscience.com](http://www.lexariabioscience.com).

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## FORWARD-LOOKING STATEMENTS

This release includes forward-looking statements. Statements as such term is defined under applicable securities laws. These statements may be identified by words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions. Such forward-looking statements in this press release include, but are not limited to, statements by the company related to strategic plans for 2021 and successfully executing its four core areas of business focus. Such forward-looking statements are estimates reflecting the Company's best judgment based upon current information and involve a number of risks and uncertainties, and there can be no assurance that the Company will actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements. As such, you should not place undue reliance on these

forward-looking statements. Factors which could cause actual results to differ materially from those estimated by the Company include, but are not limited to, government regulation and regulatory approvals, managing and maintaining growth, the effect of adverse publicity, litigation, competition, scientific discovery, the patent application and approval process, potential adverse effects arising from the testing or use of products utilizing the DehydraTECH technology, the Company's ability to maintain existing collaborations and realize the benefits thereof, and other factors which may be identified from time to time in the Company's public announcements and periodic filings with the US Securities and Exchange Commission on EDGAR. There is no assurance that existing capital is sufficient for the Company's needs or that it will be able to raise additional capital. There is no assurance the Company will be capable of developing, marketing, licensing, collaborating with third parties or selling any products containing any active ingredient or drug. There is no assurance that any planned corporate activity, research and development, scientific research or study, business venture, letter of intent, technology licensing pursuit, patent application or allowance, consumer study, or any initiative will be pursued, or if pursued, will be successful: industry-wide, these initiatives often fail and, in some cases, may require amendments, revisions or repeating as appropriate to reach successful outcomes. There is no assurance that any of Lexaria's postulated uses, benefits, or advantages for the patented and patent-pending technology will in fact be realized in any manner or in any part or be defensible. No statement herein has been evaluated by the Food and Drug Administration (FDA). Lexaria-associated products are not intended to diagnose, treat, cure or prevent any disease.

Any forward-looking statements contained in this release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

*The CSE has not reviewed and does not accept responsibility for the adequacy or accuracy of this release.*

**SOURCE:** Lexaria Bioscience Corp.

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