**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **September 7, 2021**

# LEXARIA BIOSCIENCE CORP.

(Exact name of registrant as specified in its charter)

| **Nevada** | **000-52138** | **20-2000871** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **100 – 740 McCurdy Road, Kelowna, BC Canada** | **V1X 2P7** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code **(250) 765-6424**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | LEXX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | LEXXW | The Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01 Other Events**

On September 7, 2021, Lexaria Bioscience Corp. ("Lexaria") announced the partial results from its human clinical study HYPER-H21-2 which evaluated DehydraTECH™ processed cannabidiol ("CBD") in a 24 hour study of volunteers with mild to moderate hypertension.

On September 8, 2021, Lexaria announced that it had commenced the process for preparing an Investigational New Drug application for the purposes of filing same with the Food and Drug Administration with respect to registering its DehydraTECH-processed CBD as a pharmaceutical treatment for hypertension.

**Item 9.01 Financial Statements and Exhibits**

| | |
|---|---|
| 99.1 | Press Release dated September 7, 2021 |
| 99.2 | Press Release dated September 8, 2021 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**LEXARIA BIOSCIENCE CORP.**

*/s/ Chris Bunka*
**Chris Bunka**
CEO, Principal Executive Officer

Date: September 8, 2021

**EXHIBIT 99.1**

**Lexaria's Human Clinical Study Delivers Effective and Safe Blood Pressure Reduction Results over 24-hour Ambulatory Period**

*Human Clinical Study HYPER-H21-2 evidences up to a remarkable 23% decrease in blood pressure with patented DehydraTECH-CBD relative to placebo*

**Kelowna, British Columbia – September 7, 2021** – Lexaria Bioscience Corp. (Nasdaq: LEXX) (Nasdaq: LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms is extremely pleased to issue initial results from human clinical study HYPER-H21-2 evaluating DehydraTECH$^{TM}$-processed cannabidiol ("CBD") for potential application against hypertension. Partial results related to blood pressure ("BP") are being released today, while additional BP subset analyses, sleep quality and all other data analyses are in progress and will be reported upon when complete.

At selected times during the 24-hour study, volunteers with mild to moderate hypertension averaged as much as a 20 mmHg (i.e., 23%) decrease in BP relative to placebo.

Over the 24-hour ambulatory monitoring period, volunteers averaged a significant reduction of 7.0% ($p < 0.001$) in systolic pressure with DehydraTECH-CBD relative to placebo as shown below in Figure 1.

*Figures 1, 2, and 3 below: Changes in 24-hr ambulatory systolic pressure (ΔSBP), mean arterial pressure (ΔMAP) and diastolic pressure (ΔDBP) between placebo (blue) and DehydraTECH-CBD (purple). Data are grouped means (n=16) with linear regression denoted by the trend lines. Timing of the three administered doses of DehydraTECH-CBD (150 mg CBD x 3 dosing intervals) is indicated by the vertical arrows.*

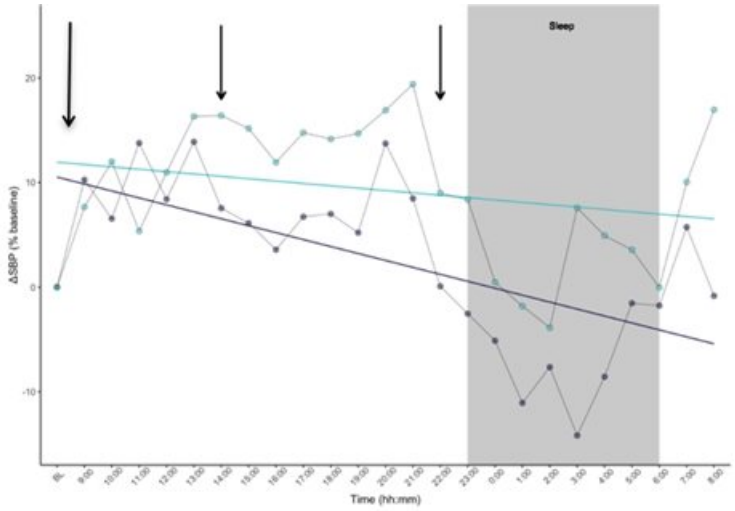


*Fig 1*

Over the 24-hour ambulatory monitoring period, volunteers averaged a significant reduction of 5.3% ($p < 0.001$) in MAP with DehydraTECH-CBD relative to placebo, as shown below in Figure 2.

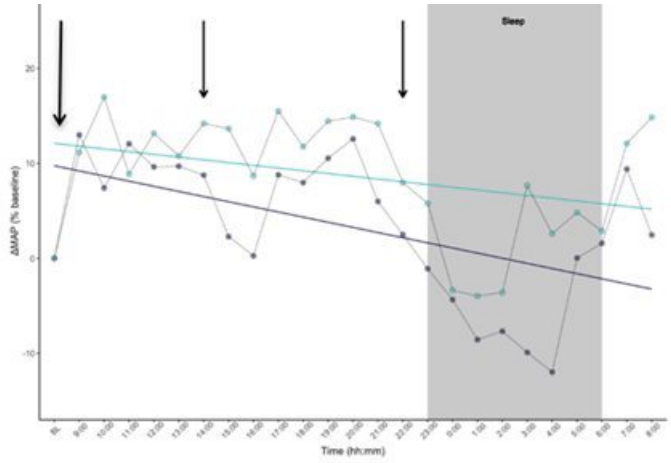


*Fig 2*

Over the 24-hour ambulatory monitoring period, volunteers averaged a significant reduction of 3.5% in diastolic pressure relative to an increase in diastolic pressure (-0.8 vs. +2.7; $p<0.001$) from baseline with DehydraTECH-CBD relative to placebo, as shown below in Figure 3.

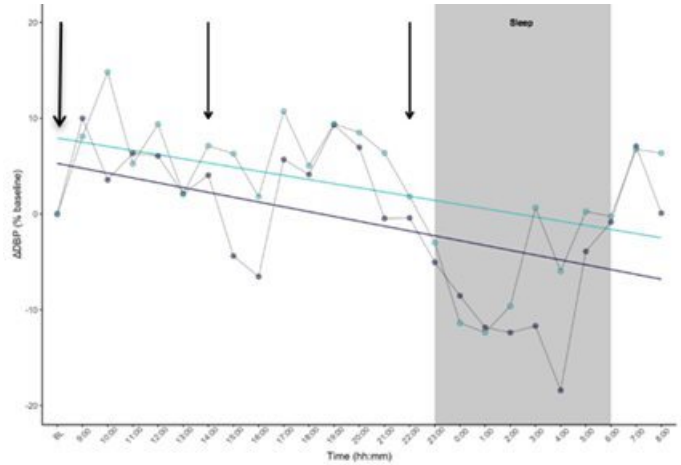


*Fig 3*

Lead investigator Dr. Phil Ainslie, Professor, School of Health and Exercise Sciences and Co-Director, Centre for Heart, Lung & Vascular Health, University of British Columbia Okanagan, and Canada Research Chair in Cerebrovascular Physiology, commented, "These improvements in BP results are particularly remarkable given the fact that many existing drugs used to treat hypertension require several weeks of treatment and/or combination dosing before they produce comparable reductions in blood pressure.

"Over the initial 24 hours, Lexaria's 2021 hypertension program is now delivering blood pressure reduction results competitive with – and in some cases even superior to – established oral pharmaceutical hypertension drugs," said Chris Bunka, CEO of Lexaria. "DehydraTECH-CBD demonstrated a sustained and augmented effect upon blood pressure attenuation throughout the day, indicating effectiveness of the repeat dosing treatment schedule used in this study."

DehydraTECH-CBD triggered its most significant effects upon BP attenuation through the overnight period while subjects slept and in the early morning period. This observation could have tremendous value therapeutically as these periods of the day are most often associated with cardiac stress and infarct events in hypertensive patients when people rise suddenly from and/or become increasingly active relative to the supine/sleeping state.

Analysis of the physical activity levels of the volunteers with mild to moderate hypertension during the 24-hour monitored period showed no significant differences in activity between the placebo and the DehydraTECH-CBD treated volunteers, indicating that the observed differences in BP were not due to disparate physical movement or demands.

Other studies of coronary heart disease ("CHD") have concluded that *"lowering systolic pressure by 10 mmHg or diastolic pressure by 5 mmHg using any of the main classes of drugs reduced CHD events (fatal and nonfatal) by about a quarter and stroke by about a third, regardless of the presence or absence of vascular disease and of pretreatment BP. Heart failure is also reduced by about 25%.*"

Lexaria was also pleased that, as in past studies, its DehydraTECH-CBD was well tolerated by all subjects, with no serious adverse events or side effects observed or reported or incidence differences between groups. Over 100 million adult Americans have high blood pressure, but only one in four of those have the condition under control. Many patients stop taking their medications because of troublesome side effects: some diuretics can cause excessive urination, beta blockers can cause erectile dysfunction, calcium-channel blockers can cause leg swelling, and ACE inhibitors can lead to persistent cough. Lexaria believes that its DehydraTECH-CBD may introduce a more tolerable anti-hypertensive treatment option that may be used alone or in combination with other medications, to reduce BP with fewer discouraging and unwanted side effects.

**Next Steps**

Data analysis from this study is continuing and additional outcomes will be reported upon when complete. On July 29, 2021, Lexaria reported it was "optimistic that repeat dosing such as this over a sustained period may further enhance efficacy," and is delighted to have now shown this by way of the 3-dose and 24-hour monitoring used in study HYPER-H21-2. The results of these first two human clinical hypertension studies are being carefully evaluated and considered before Lexaria's third planned human clinical (pulmonary) hypertension study of 2021 begins, expected this Fall.

With the positive results generated from these first two 2021 human clinical studies, Lexaria reaffirms its intention to also pursue a fourth hypertension study. Study design considerations are already underway with expectations to include a larger hypertensive population, regular monitoring of BP over at least a 4-week duration designed to monitor longer term performance and tolerability, and measurements of inflammatory and oxidative markers as well as overall vascular health.

Given the remarkable reduction in BP of up to 20 mmHg, Lexaria will be investigating whether similar decreases might be achievable over longer periods of time which could lead to effective long term BP treatment strategies.

**About DehydraTECH-CBD**
DehydraTECH-CBD is a unique CBD formulation Lexaria has developed and is optimizing based on its patented and proprietary DehydraTECH drug delivery technology. DehydraTECH is designed to improve the way active molecules enter the bloodstream upon oral ingestion. DehydraTECH has also demonstrated enhanced delivery of certain active molecules including CBD into brain tissue, which Lexaria believes to be of particular importance for the effectiveness of its DehydraTECH-CBD specifically against hypertension because of the significant influence of central mediation upon blood pressure.

**About Human Study HYPER-H21-2**
Human Study HYPER-H21-2 was conducted at a European medical research hospital. Sixteen human volunteers (8 male; 8 female) aged 45-65 with otherwise untreated pre- or mild-hypertension were given either a placebo, or three separate doses of 150 mg each of DehydraTECH-CBD over a 14-hour period and studied over a 24-hour duration. The average weight and height were 91 ± 13 kg and 173 ± 9 cm. Ambulatory blood pressure was recorded for 24 hours. Additional BP subset analyses, sleep quality and all other data analyses are in progress and will be reported upon when complete.

**CBD in the Regulatory Environment.**
CBD under the brand name Epidiolex® was approved by the FDA in June 2018 for treating certain types of pediatric seizure disorders. Recommended dosing of Epidiolex CBD is 2.5 mg per kilogram of bodyweight to begin treatment, taken twice per day, increasing to 5.0 mg per kilogram of bodyweight, taken twice per day. An average 9 year-old child weighs about 28 kg, so the FDA recommended dose of Epidiolex would initially be 140 mg, increasing to 280 mg daily for long term use. The average adult man in the US weighs 199.6 lbs (90.7kg), so if he was using CBD at that same rate, he would require 900 mg per day for a sustainable dose. The maximum FDA-approved dose of Epidiolex is 10.0 mg per kilogram of bodyweight, taken twice daily.

**Hypertension Markets**
The hypertension market is valued at $28 billion per year and is expected to continue growing as one of the world's top health problems. Geographically, some of the highest rates of growth are expected in more recently industrialized nations such as China and India. Over 1.1 billion people worldwide suffer from hypertension – elevated blood pressure. Hypertension is a major risk factor for cardiovascular and cerebrovascular disease, and accounts for approximately 45% of cardiovascular disease mortality and morbidity worldwide.

"Among persons 50 years of age or older, isolated systolic hypertension is the most common form of hypertension, and systolic blood pressure becomes more important than diastolic blood pressure as an independent risk predictor for coronary events, stroke, heart failure, and end-stage renal disease (ESRD). The Global Burden of Disease Study identified elevated blood pressure as the leading risk factor, among 67 studied, for death and disability-adjusted life-years lost during 2010."

Drugs focused on blood pressure and related conditions are some of the highest selling drugs in the world. Lipitor, used to treat high cholesterol and reduce the risk of heart disease, has generated $94.7 billion in revenue from 1992 until 2017. Plavix, used to prevent heart attack and stroke, has sold $46.5 billion from 1992 until 2017. There are several hypertension drugs that each generate $1 billion per year or more in revenue.

**About Lexaria Bioscience Corp.**

Lexaria Bioscience Corp.'s patented drug delivery technology, DehydraTECH™, improves the way active pharmaceutical ingredients (APIs) enter the bloodstream by promoting more effective oral delivery. Since 2016, DehydraTECH has repeatedly demonstrated the ability to increase bio-absorption with cannabinoids and nicotine by 5-10x and, in some instances with cannabinoids by as much as 27x compared to standard industry formulations, reduce time of onset from 1 - 2 hours to minutes, and mask unwanted tastes; and is also being evaluated for orally administered anti-viral drugs, non-steroidal anti-inflammatory drugs (NSAIDs), and more. DehydraTECH has also evidenced an ability to deliver some drugs more effectively across the blood brain barrier. Lexaria operates a licensed in-house research laboratory and holds a robust intellectual property portfolio with 21 patents granted and over 50 patents pending worldwide. For more information, please visit www.lexariabioscience.com.

**CAUTION REGARDING FORWARD-LOOKING STATEMENTS**

This press 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 relating the Company's ability to carry out research initiatives, receive regulatory approvals or grants or experience positive effects or results from any research or study. 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, delays or cancellations of planned R&D that could occur related to pandemics or for other reasons, 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 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. 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.

**INVESTOR CONTACT:**
ir@lexariabioscience.com
Phone: 250-765-6424, ext 202

**EXHIBIT 99.2**

**Lexaria Begins Investigational New Drug (IND) Enabling Program for DehydraTECH-CBD for Hypertension**

*Positive results using DehydraTECH-CBD support progressing to FDA IND application*

**Kelowna, British Columbia – September 8, 2021** – Lexaria Bioscience Corp. (Nasdaq: LEXX) (Nasdaq: LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms today announced it is formally beginning the process towards an Investigational New Drug ("IND") application filing with the Food and Drug Administration ("FDA") with its DehydraTECH-processed cannabidiol ("DehydraTECH-CBD") as a prospective registered pharmaceutical treatment for hypertension.

Lexaria has retained the services of an expert regulatory affairs and quality assurance consultancy group that will help prepare Lexaria for a pre-IND meeting with the FDA, as well as with designing the necessary non-clinical, clinical and related product development IND-enabling work to be completed in advance of the IND filing.

Lexaria's new IND enabling program is made possible through successfully completed studies that have provided support for more ambitious commercial goals. Recently achieved successful results from two 2021 human clinical pharmacodynamic hypertension studies and a 2018 human clinical pharmacokinetic ("PK") study, along with a number of successful animal studies demonstrating PK performance and molecular characterization work completed through Canada's National Research Council, have together established a strong body of evidence for Lexaria's DehydraTECH-CBD. These studies have shown that DehydraTECH-CBD demonstrates superior bioabsorption upon oral administration and is effective at reducing blood pressure with no significant unwanted side effects.

Provided that ongoing and upcoming studies continue to deliver favorable results, and that IND and other approvals from regulators are obtained, Lexaria intends to progress to a New Drug Application ("NDA") at the appropriate time, possibly via the abbreviated 505(b)(2) pathway.

The IND application process is also expected to utilize data from the Company's third and fourth 2021 human clinical hypertension studies, whereby Lexaria hopes that these studies will contribute further valuable data to its growing information package.

Lexaria will provide details on the timing and specifics of its planned pre-IND meeting and of the non-clinical, clinical and related product development IND-enabling work program elements to be completed in advance of and to culminate in IND filing as these details become available.

In addition, Lexaria is evaluating whether additional therapeutic indications for DehydraTECH-CBD might be pursued with the FDA in due course.

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Fewer than 1 person in 4 with hypertension have successfully controlled their blood pressure through medications, meaning the potential market for hypertension drugs is much larger than $28 billion per year if an affordable drug was available with few or no side effects. Lexaria believes that its DehydraTECH-CBD may introduce a more tolerable anti-hypertensive treatment option that may be used alone or in combination with other medications, to reduce BP with fewer discouraging and unwanted side effects. Lexaria would seek to satisfy this currently unmet demand and in doing so could expand the overall hypertension market.

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