

Drug Delivery Platform Innovator
With Multiple Mainstream Applications

Investor Presentation Q1 2024

Lexaria Bioscience Corp.

NASDAQ:LEXX | NASDAQ:LEXXW

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No statement within has been evaluated by the Food and Drug Administration, and no product or service is yet commercially approved and intended to diagnose, treat, cure or prevent any disease.



- 1. Lexaria's Drug Delivery Platform Technology
- 2. DehydraTECH Pipeline and Market Investigations
- 3. DehydraTECH for Hypertension
- 4. DehydraTECH for Diabetes and Weight Loss
- 5. Management, Directors and Advisors
- 6. Investment Highlights and Financial Information
- 7. Appendix: Scientific Data







# Lexaria's Drug Delivery Platform Technology - DehydraTECH

### Lexaria's **DehydraTECH**:

- is a versatile drug delivery platform technology that provides a more predictable time of delivery of Active Pharmaceutical Ingredients ("APIs") into the **bloodstream** and into **brain tissue**;
- enhances the pharmacokinetic performance of APIs, increasing bioavailability, improving speed of onset and increasing brain absorption;
- has multiple R applications in hypertension, diabetes and weight loss and others;
- can be applied to topicals and multiple oral/intraoral product **formats** such as tablets, capsules, oral suspensions, mouthmelts and others;
- focused on commercialization through partnerships and licensing
- has been awarded 39 patents granted and many more pending around the world for use with a broad range of bioactive molecules

## **Upcoming 2024 Catalysts:**

### **Hypertension:**

 FDA Investigational New Drug opening study HYPER-H23-1

#### **GLP-1** (Diabetes/Weight Loss):

- Human Pilot Study #2
- Animal Study WEIGHT-A24-1
- Human Pilot Study #3
- Chronic Dosing Human Study
- Long Term Stability Study



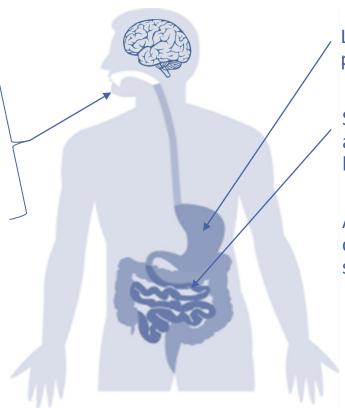
# **DehydraTECH Proposed Mechanism of Action**

### **Dissolvable Orals**

LCFAs are believed to block and shunt associated APIs away from bitter taste receptors for APIs that need flavor masking<sup>(1)</sup>

LCFAs influence permeability in the oral cavity<sup>(2)</sup> (i.e., sublingually and/or buccally)

Adjunct ingredients are added to enhance oral cavity permeability performance



## **Ingestible Solid Orals / Liquids**

LCFAs influence gastric cholecystokinin production and motility<sup>(4)</sup>

Small intestine quickly absorbs LCFAassociated APIs into the bloodstream via the lymphatics bypassing first pass liver effect<sup>(5)</sup>

Adjunct ingredients added to enhance stomach or small intestine uptake depending on desired site of absorption

### **Enhanced brain absorption**

Once absorbed systemically through dissolvable or solid oral form factors, LCFA-associated APIs are believed to enter brain preferentially through fatty acid transport proteins<sup>(3)</sup>

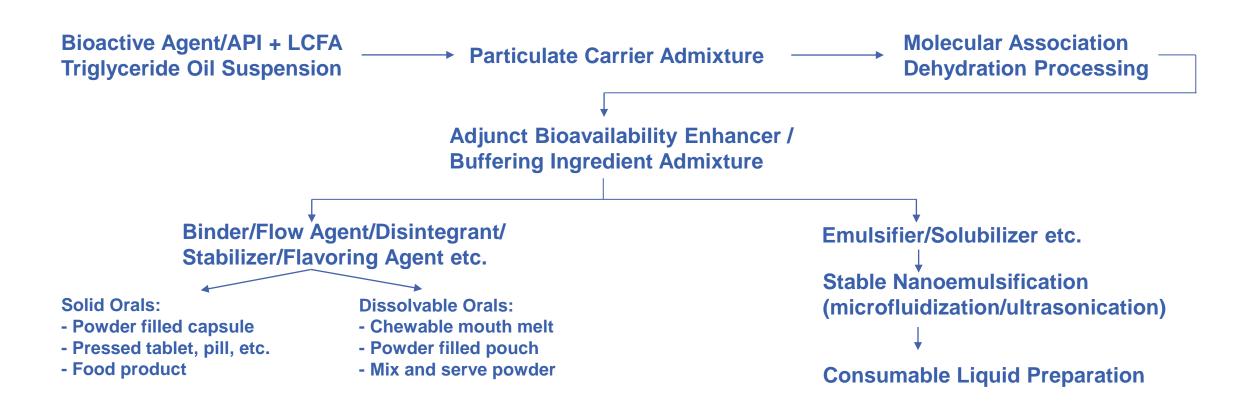
LCFA = Long Chain Fatty Acid





# **DehydraTECH Drug Delivery Technology Overview**

✓ Speeds onset ✓ Increases bioavailability ✓ Improves potency/effectiveness/palatability/tolerability



LCFA = Long Chain Fatty Acid API = Active Pharmaceutical Ingredient



# **DehydraTECH - Patented Technology Potential Benefits**

Masks unwanted taste (1)

Improves speed of onset

Increases bioavailability

Increases brain absorption

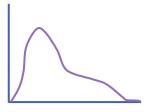
Reduces Drug
Administration Costs



Eliminates the need for sugar-filled edibles



Effects are felt in minutes<sup>(2)</sup>



Much more effective at delivering drug into bloodstream<sup>(3)</sup>



Testing suggests up to 17x improvement<sup>(4)</sup>



Higher ratio of drug delivery expected to lower overall drug costs

Patented drug delivery technology improves oral administration of Active Pharmaceutical Ingredients







<sup>(1)</sup> Based on subjective clinical testing in 29 human volunteers with CBD, THC and nicotine formulations and hundreds of thousands of commercial product servings of CBD and THC formulations by Lexaria's licensing partners.

<sup>(2)</sup> Based on subjective clinical testing in 82 human volunteers with CBD, THC and nicotine formulations and hundreds of thousands of commercial product servings of CBD and THC formulations by Lexaria's licensing partners.

<sup>(3)</sup> Based on objective clinical testing in 13 human volunteers with CBD formulations, and in vivo animal testing in 316 rodents with CBD and nicotine formulations

<sup>(4)</sup> https://ir.lexariabioscience.com/news-events/press-releases/detail/128/lexaria-issues-successful-results-from-first-2021-study



## **Commercial Opportunities**

- Lexaria management and directors have extensive experience in building relationships with "Fortune 500" companies
- Actively developing **lead product pipeline candidates** in the areas of:
  - Hypertension and potentially heart disease
  - GLP-1 drugs/diabetes and weight loss
- Lexaria is currently engaged with other companies, exploring opportunities with their specific APIs of interest
- Lexaria out-licenses its technology in exchange for up-front fees, milestone payments and/or royalty payments
- Lexaria is generating revenues now through the manufacture of corporate customer specified DehydraTECH formulations





# **DehydraTECH Pipeline**

Identification	Modality	Therapeutic / Commercial Use	Potential Indication(s)	Formulation>Animal PK>	Status in vitro / Animal PD	> Human POC> Registered Trials
DehydraTECH-CBD	Small Molecule	Cardiovascular	St. 1/2 Hypertension*			<b>──</b>
DehydraTECH-Nicotine	Small Molecule	Nicotine Replacement	N/A			
DehydraTECH-GLP-1	Peptide	Metabolic Disorders	Diabetes / Weight Loss Management			
DehydraTECH-CBD	Small Molecule	Metabolic Disorders	Diabetes / Weight Loss Management			2024 Objectives (red): - HYPER-H23-1 Phase
DehydraTECH-CBD	Small Molecule	Neurology	Seizure Disorders			Ib IND Authorization and Execution** - Comprehensive
DehydraTECH-Antiviral	Small Molecule	Antiviral	HIV/Covid-19/etc.		_	series of animal and human acute and
DehydraTECH-PDE5	Small Molecule	Cardiovascular	Erectile Dysfunction			chronic dosing GLP-1 PK/PD/POC studies**
DehydraTECH-Estradiol	Small Molecule	Hormone Therapy	HRT and Menopause			

PK = Pharmacokinetic

PD = Pharmacodynamic

POC = Proof of Concept

CBD = Cannabidiol

CPG = Consumer Packaged Good product

GLP-1 = Glucagon-Like Peptide 1 Agonists
PDE5 = Phosphodiesterase 5

HIV = Human Immunodeficiency Virus HRT = Hormone Replacement Therapy

\*For the treatment of stage 1 or stage 2 hypertensive patients not adequately managed with existing treatments

\*\* Pending Additional Funding

**Bold black line items signify active 2024 programs** 









# **Market Value of 2024 DehydraTECH Investigations**

Pharmacokinetic studies are evaluating **DehydraTECH's ability to improve quantity** of drug delivered and **speed** with which it is delivered, **in all of these areas:** 

	Size		<b>Future Size</b>	
DehydraTECH Markets	US \$bn	Year	US \$bn	Year
Diabetes <sup>(1)</sup>	79.3	2023	134.1	2030
Cardiovascular Drugs(2)	85.8	2023	115.8	2028
GLP-1(3)	18.0	2023	100.0	2028
Epilepsy <sup>(4)</sup>	7.0	2023	9.5	2032
Human Hormones(5)	3.7	2023	7.3	2032
PDE5 Inhibitors(6)	3.4	2023	6.1	2032

<sup>(1)</sup> https://www.fortunebusinessinsights.com/industry-reports/diabetes-drugs-marke

<sup>(2)</sup> https://www.researchandmarkets.com/reports/5410400/global-cardiovascular-drugs-market-2023-2028

<sup>3)</sup> https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-rivals-see-room-compete-100-bln-weight-loss-drug-market-2023-05-04/

<sup>4)</sup> https://www.precedenceresearch.com/epilepsy-drug-market

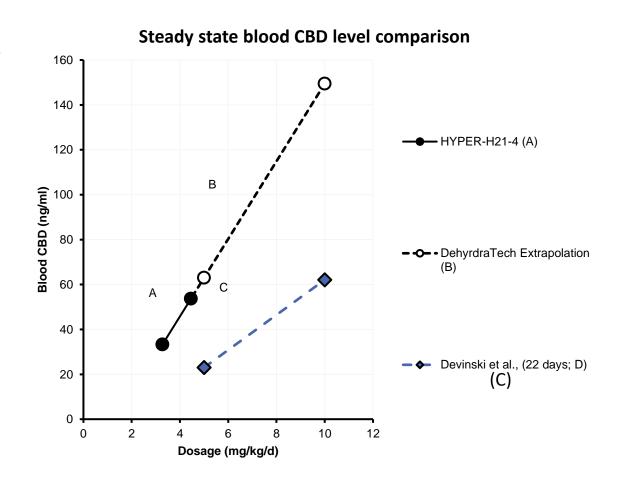
https://www.globenewswire.com/en/news-release/2023/05/23/2674523/0/en/8-1-CAGR-of-Human-Growth-Hormone-Market

<sup>(6)</sup> https://www.globenewswire.com/en/news-release/2023/04/06/2642598/0/en/Erectile-Dysfunction-Drugs-Market-Value



# **DehydraTECH-CBD PK compared to Epidiolex®**

- HYPER-H21-4 evidenced <u>superior steady-state</u> <u>pharmacokinetics</u> relative to <u>Epidiolex</u> in published literature comparison;
- Study assessed 3.38 mg/Kg and 4.46 mg/Kg DehydraTECH-CBD daily dose levels over a 5 week treatment period (2.5 wks / dose period);
- Almost 3X higher CBD levels shown in bloodstream at 4.46 mg/Kg dose when compared to published 5 mg/Kg Epidiolex dose and extrapolated to 10 mg/Kg dose<sup>(1)</sup>;

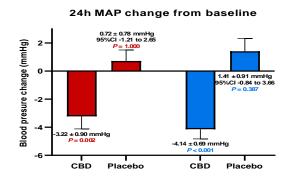


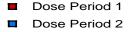


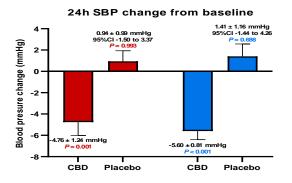


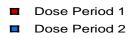
# **DehydraTECH for Stage 1 and 2 Hypertension**

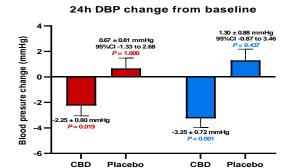
- Randomized, placebo-controlled investigator-initiated study HYPER-H21-4 in 66 patients with stage 1 or 2 hypertension
- 5-week treatment duration (i.e., a 2.5-week dose period @ 3.38 mg/Kg TID followed by 2.5-week dose period @ 4.46 mg/Kg TID);
- <u>Significant reductions</u> shown in mean arterial (MAP), systolic (SBP) and diastolic blood pressure (p<0.05);
- Other published research has shown reductions of ~4.6 mmHg for SBP and ~2.2 mmHg for DBP as clinically significant to reduce risk of MI, stroke and CHF.
   DehydraTECH-CBD exceeded these thresholds;
- Potential <u>novel mechanism</u> of action in reducing blood pressure and a <u>reduction in</u> pro-inflammatory biomarkers;
- Enhanced <u>central delivery</u> attributes of **DehydraTECH** may improve <u>BP regulation</u>;
- Study also suggested potential additive BP reduction benefits with standard of care medications; and
- Zero serious adverse events were recorded.

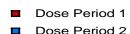
















# **DehydraTECH FDA Phase 1b IND Program**

- <u>Successful pre-IND meeting</u> with the FDA in 2022 with <u>505(b)(2)</u> NDA regulatory pathway confirmed;
- <u>Received FDA clearance</u> for IND opening study HYPER-H23-1:
  - Phase 1b randomized, double-blind, placebo-controlled study of the safety, pharmacokinetics, and pharmacodynamics of **DehydraTECH**-CBD for the treatment of stage 1 or 2 hypertension;
- Only a handful of <u>other published studies</u> have investigated resting blood pressure impacts of CBD; none have reported sustained reductions except **DehydraTECH**-CBD;
- FDA has issued <u>clear guidelines</u> defining the need for new antihypertensives that offer novel modes of action;
- Treatment of Stage 1 or 2 hypertensive patients not adequately managed with existing treatments.

Possible Iture Studie

- Lexaria envisions potential additional new human clinical studies of **DehydraTECH**-CBD under IND based on its animal study successes:
  - Study EPIL-A21-1 demonstrated suppressed seizure activity at lower doses and more rapidly than Epidiolex
  - Study DIAB-A22-1 evidenced <u>suppressed body weight</u>, <u>improved triglyercide/cholesterol levels</u> and <u>reduced blood glucose levels</u>



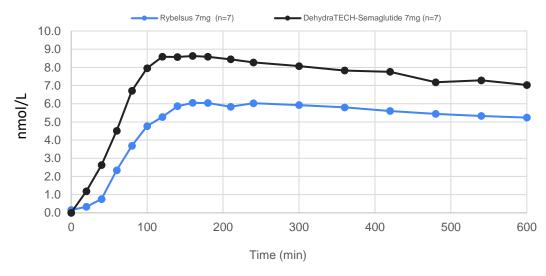




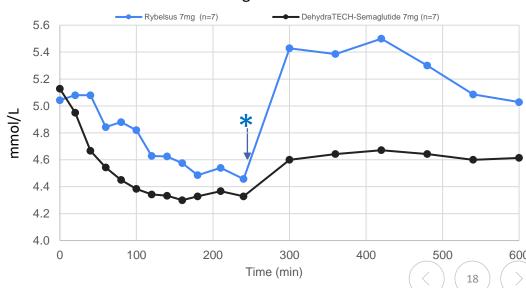
# **DehydraTECH for Diabetes and Weight Loss**

- Randomized, cross-over, single-dose, Investigator-initiated pilot study in 7 healthy volunteers (completed in 2023):
  - Rybelsus 7mg tablets vs. DehydraTECH-Semaglutide 7 mg compound formulated capsules;
- Blood sampled at 18 intervals from T=0 to T=600 min and again at T=24hr post-dose follow up (figures do not show T-24hr data);
- Higher blood semaglutide levels / AUC demonstrated throughout the study duration with <u>DehydraTECH</u> (p<0.05);</li>
- Blood glucose levels lower throughout the study with DehydraTECH (p<0.05); most notably post prandially\*;</li>
- Enhanced <u>central delivery</u> attributes of **DehydraTECH** may have contributed to the pronounced GLP-1 effect profile witnessed;
- Apparent improvements in gastrointestinal tolerability witnessed:
  - Zero instances of moderate nausea/diarrhea with DehydraTECH-Semaglutide;
  - Moderate nausea (n=2) and moderate diarrhea (n=1) only reported with Rybelsus treatment.

#### Blood semaglutide levels



#### Blood glucose levels





# 2024 Planned GLP-1 Work Program

### Human Pilot Study #2 (Targeted start: April)

• Up to 8 healthy human volunteers; placebo-controlled investigation that will compare three dose formulations each at a 7 mg semaglutide dose. Study an oral dissolvable **DehydraTECH**-semaglutide tablet formulation (dissolvable into sublingual/buccal tissue) to determine whether GLP-1 drug absorption via this route is effective and well tolerated. Tolerability, blood levels of semaglutide, and blood glucose levels will all be evaluated.

### **Animal Study WEIGHT-A24-1** (Targeted start: April)

• An obese rat diabetic-conditioned study with 12 study arms and 6 animals per arm. Study will run for 12 weeks to evaluate PK, body weight, blood glucose and brain tissue to help determine whether **DehydraTECH** processing results in higher brain absorption than non-**DehydraTECH** arms. **DehydraTECH** formulations of semaglutide and liraglutide, alone and together with **DehydraTECH**-CBD, will be evaluated. Lexaria will also evaluate **DehydraTECH**-processed semaglutide with and without the salcaprozate sodium ("SNAC") technology currently found within Rybelsus® tablets.

### **Human Pilot Study #3** (Targeted start in May/June)

• Up to 8 healthy human volunteers; a single dose of oral ingested tirzepatide (Zepbound® by Eli Lilly) to evaluate tolerability, PK, and blood sugar. Zepbound® is currently administered by injection only and will be used as the tirzepatide input material for production of the **DehydraTECH**-tirzepatide capsules. This study will evaluate **DehydraTECH** effectiveness in humans with a dual action GLP-1 + glucose-dependent insulintropic peptide ("GIP") drug while also doing so without the SNAC ingredient found in the Rybelsus® semaglutide composition from Human Pilot Studies 1 and 2.

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# 2024 Planned GLP-1 Work Program (cont'd)

### Chronic Dosing Human Study (Targeted start Q3)

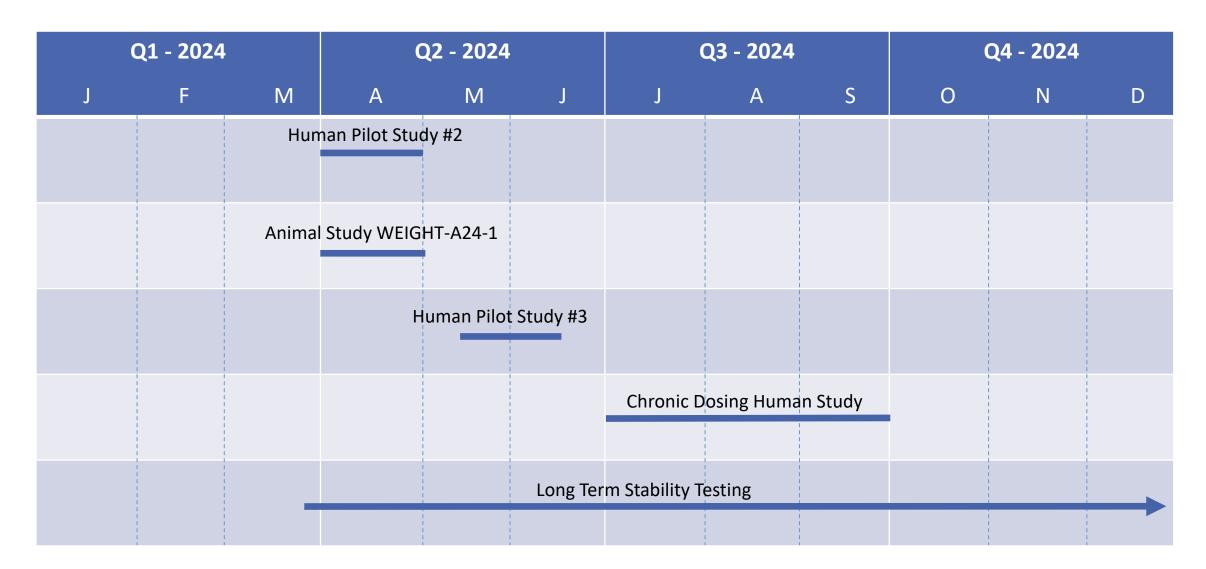
• 70 to 90 pre-diabetic and type-2 diabetic human patients. Duration of 12 weeks to evaluate tolerability, PK, weight loss, blood sugar levels and more. The primary goal of this study will be to compare DehydraTECHprocessed semaglutide capsules (from compound-formulated Rybelsus® tablets as the semaglutide input material) to **DehydraTECH**-CBD capsules alone - and together in combination - relative to a placebo control over an extended period of time. Inclusion of **DehydraTECH**-CBD in this study will be undertaken to determine if the improvements in glycemic control and weight loss witnessed in Lexaria's previous animal study are evidenced in humans.

### **Long Term Stability** (Targeted start Q1)

• Study the chemical and microbiological purity and stability of select **DehydraTECH** compositions that it prepares for the above planned upcoming animal and human studies over an extended duration of 6-12 months. Along with improved tolerability, PK and efficacy performance, long term stability is crucial if oral variants of GLP-1 drugs are to be seriously considered as replacements for currently injectable versions of these drugs.



# **GLP-1 R&D Program Targeted Start Dates**







## **Executives, Directors, and Advisors With Drug Delivery Technology and Capital Markets Expertise**



#### Chris Bunka Chairman & CFO

- Serial entrepreneur involved in several private and public companies since the late 1980's
- Extensive experience in the capital markets, corporate governance, M&A and finance
- Named inventor on multiple patent innovations



#### Julian Gangolli Strategic Advisor

- Former President of GW Pharmaceuticals USA and Allergan N.A
- Extensive US and International executive level experience in Large Pharma, Specialty Pharmaceutical, and Start-Up Biotechnology environments
- Board of Directors member of three NASDAQ traded pharmaceutical companies; Revance Therapeutics, Krystal **Biotech and Outlook Therapeutics**



#### John Docherty, M.Sc. President

- Specialist in development of drug delivery technologies
- Former President and COO of Helix BioPharma Corp. (TSX: HBP)
- Named inventor on multiple issued and pending patents
- Pharmacologist and toxicologist



### **Dr. Philip Ainslie** Scientific & Medical **Advisor**

- Co-Director for the Centre for Heart, Lung and Vascular Health, Canada
- Research Chair in Cerebrovascular Physiology and Professor, School of Health and Exercise Sciences, Faculty of Health and Social Development at the University of British Columbia











## **Investment Highlights**

### **Multiple Mainstream Applications In Large Markets**

### **Upcoming 2024 Catalysts**

### Commercialization **Through Licensing and Partnerships**

- DehydraTECH is a versatile drug delivery platform
- DehydraTECH offers faster and more effective drug absorption into bloodstream and brain tissues
- DehydraTECH pipeline addressing serious unmet patient needs with substantial market potential
- Large addressable market opportunities in hypertension, GLP-1 drugs and other APIs

### **Hypertension:**

IND opening study HYPER-H23-1

### **GLP-1** (Diabetes/Weight Loss):

- Human Pilot Study #2
- Animal Study WEIGHT-A24-1
- Human Pilot Study #3
- Chronic Dosing Human Study
- Long Term Stability Study

- Extensive experience with drug delivery technology; capital markets; "Fortune 500" relationships
- License agreements in place
- 39 patents granted and many more patent applications pending around the world







## Financial Information(1)

## NASDAQ:LEXX | NASDAQ:LEXXW

**Shares Outstanding** 12.4 million

**Fully Diluted** 19.5 million

US \$3.45 **Share Price** 

**Insider Ownership** 5.0%(2)

Average Volume 387,225<sup>(3)</sup>

US \$42.8 million Market Cap

US \$3.6 million Last Financing (February 2024)

US ~\$1.9 million Cash and Equivalents (Q1 – November 30, 2023)

US \$0 Debt

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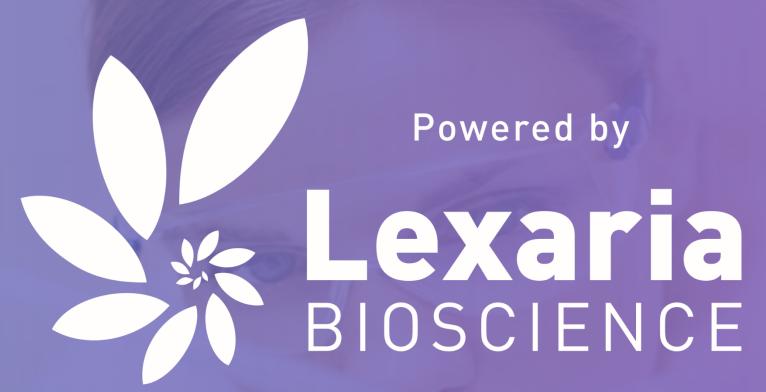
ir@lexariabioscience.com

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- (1) As of 02/29/2024, source Nasdaq
- (2) Does not include derivative holdings, as of August 31, 2023
- (3) 1-month average volume, as of February 29, 2024







Drug Delivery Platform Innovator
With Multiple Mainstream Applications

# **CONTACT:**

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## **DehydraTECH Demonstrates Higher Brain Perfusion with Nicotine**

- Lexaria's **DehydraTECH** technology delivered 195% more nicotine orally into exsanguinated brain tissue in rodent study;
- Lexaria's formulation was 4x faster at reaching its peak level in brain tissue than the concentrationmatched control formulation; and

	Lexaria Formulation	Control Formulation	
Cmax (ng/g)	1,260 ± 200	427 ± 66.5	
Tmax (hr)	1.0	4.0	
T1/2 (hr)	21.6	ND	
MRTlast (hr)	9.24	7.03	
AUClast (hr.ng/g)	12,999 ± 1252	5,881 ± 538	

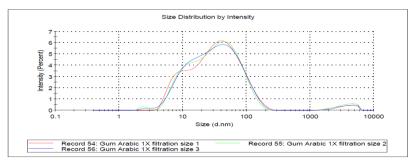
• Similar findings have also been documented with other **DehydraTECH**-processed APIs such as <u>THC</u> and CBD.



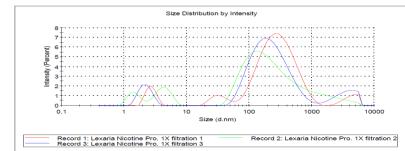
# **DehydraTECH Molecular Characterization Studies**

• DLS and Zeta Potential screening shows formation of unique, negatively charged nanoparticles with **DehydraTECH**-nicotine formulation compared to constituent subparts

#### **Gum Arabic**

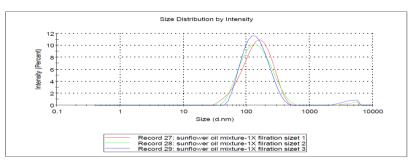


#### Nicotine Polacrilex

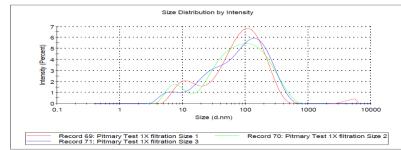


#### Zeta **Product** Size (nm) **Potential** (mV) **Gum Arabic** 42 -19 **Nicotine** 328 -15 Polacrilex **LCFA** Oil/Nicotine 163 -30 mixture Test Article 117 -30

#### LCFA Oil + Nicotine Polacrilex

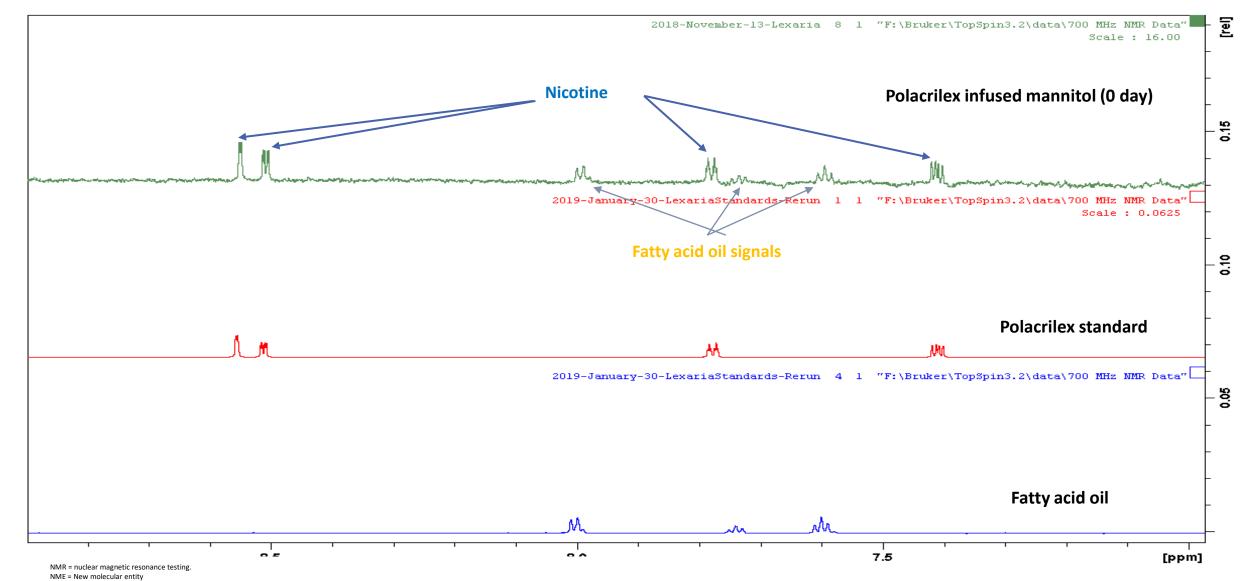


#### DehydraTECH-Nicotine ("Test Article")





## NMR Testing – No Covalently Bond NME with DehydraTECH-Nicotine







## **List of Scientific Publications**

### For more information visit: Lexaria Research

#### International Journal of Molecular Sciences - June 2023

 Differences in Plasma Cannabidiol Concentrations in Women and Men: A Randomized, Placebo-Controlled, Crossover Study.

#### Advances in Therapy – June 2023

• The Influence of Oral Cannabidiol on 24-h Ambulatory Blood Pressure and Arterial Stiffness in Untreated Hypertension: A Double-Blind, Placebo-Controlled, Cross-Over Pilot Study.

#### Cannabis and Cannabinoid Research — April 2023

• Chronic Effects of Oral Cannabidiol Delivery on 24-h Ambulatory Blood Pressure in Patients with Hypertension (HYPER-H21-4): A Randomized, Placebo-Controlled, and Crossover Study.

#### Journal of Personalized Medicine – June 2022

 Chronic Effects of Effective Oral Cannabidiol Delivery on 24-h Ambulatory Blood Pressure and Vascular Outcomes in Treated and Untreated Hypertension (HYPER-H21-4): Study Protocol for a Randomized, Placebo-Controlled, and Crossover Study.

#### Journal of Functional Foods - November 2023

• Antihypertensive effects of CBD are mediated by altered inflammatory response: A sub-study of the HYPER-H21-4 trial.

#### Biomedicine & Pharmacotherapy – June 2023

• Effects of CBD supplementation on ambulatory blood pressure and serum urotensin-II concentrations in Caucasian patients with essential hypertension: A sub-analysis of the HYPER-H21-4 trial.

#### Pharmaceuticals - April 2023

• Trial of a Novel Oral Cannabinoid Formulation in Patients with Hypertension: A Double-Blind, Placebo-Controlled Pharmacogenetic Study.

#### Biomedicine & Pharmacotherapy — April 2023

• CBD supplementation reduces arterial blood pressure via modulation of the sympatho-chromaffin system: A substudy from the HYPER-H21-4 trial.

#### Advances in Therapy – September 2019

• Examination of a New Delivery Approach for Oral Cannabidiol in Healthy Subjects: A Randomized, Double-Blinded, Placebo-Controlled Pharmacokinetics Study.

