

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) **January 4, 2024**

LEXARIA BIOSCIENCE CORP.

(Exact name of registrant as specified in its charter)

<u>Nevada</u> (State or other jurisdiction of incorporation)	<u>000-52138</u> (Commission File Number)	<u>20-2000871</u> (IRS Employer Identification No.)
<u>100 – 740 McCurdy Road, Kelowna, BC Canada</u> (Address of principal executive offices)		<u>V1X 2P7</u> (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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 7.01 Regulation FD Disclosure

On January 4, 2024, Lexaria Bioscience Corp. (“**Lexaria**”) announced the final results from its human pilot study (the “**Study**”) which evaluated a DehydraTECH™ processed dosage of the glucagon-like peptide-1 (“**GLP-1**”) drug semaglutide found in Rybelsus® against a parallel dosage of non-DehydraTECH processed Rybelsus®. The Study was conducted in a university research center as a cross-over design over two study visits, one in November and the second in December, whereby all seven healthy subjects were dosed with each test article.

Results from the Study indicate at all 19 blood point sample time points, that the DehydraTECH GLP-1 blood semaglutide level was higher than the Rybelsus® control sample and that peak levels of semaglutide in blood were 43% higher in the DehydraTECH GLP-1 than in the Rybelsus® control sample.

Additional results indicated that:

- subjects receiving the DehydraTECH GLP-1 processed semaglutide did not experience the side effects of moderate nausea and moderate diarrhea that the subjects taking the Rybelsus® control sample experienced
- DehydraTECH GLP-1 reduced blood glucose to lower levels than the Rybelsus® control sample and was much more effective at maintaining consistently reduced blood glucose levels even after eating a standardized meal at the 240-minute mark and a standardized snack at the 360-minute mark

Item 9.01 Financial Statements and Exhibits

99.1 [Press Release dated January 4, 2024](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: January 4, 2024

Lexaria's Patented Technology Improved the Oral Performance of the Rybelsus®-Branded GLP-1 drug Semaglutide

Final results from a human pilot study show DehydraTECH™-powered semaglutide outperforms Rybelsus®:

- Sustained higher levels of semaglutide in blood;
- Better blood glucose control;
- Faster achievement of peak drug delivery; and
- Reduced side effects.

Kelowna, British Columbia – January 4, 2024 – Lexaria Bioscience Corp. (Nasdaq: LEXX & LEXXW) (the “Company” or “Lexaria”), a global innovator in drug delivery platforms announces positive final results from its recently completed human Pilot Study #1 (the “Study”) evaluating DehydraTECH™ technology for the oral delivery of the glucagon-like peptide-1 (“GLP-1”) drug semaglutide available commercially in the branded product Rybelsus®.

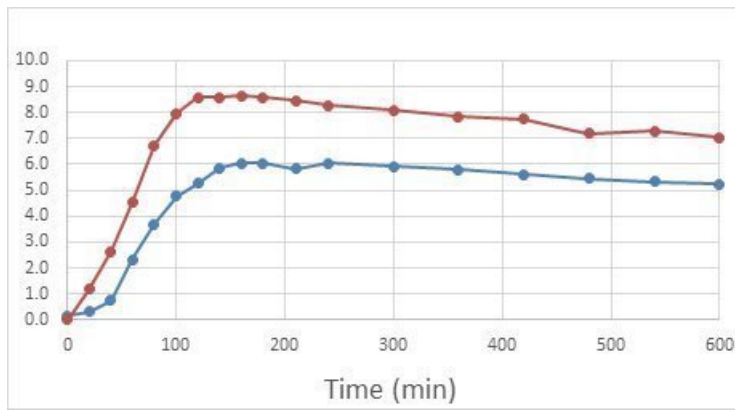
The Study was performed by a prominent university research center comparing a single 7 mg semaglutide dose of a Rybelsus® tablet (“Control”) to a matching dose from Rybelsus that had been compound formulated in capsule form using DehydraTECH processing technology enhancements (“DehydraTECH GLP-1”).

In general, the DehydraTECH processing enabled improvements in delivery of semaglutide to the bloodstream, and the improvements in controlling blood sugar were more pronounced in the final combined results of the Study than they were in the first half of the Study as reported in press releases issued [November 27](#) and [November 28](#), 2023.

Blood Levels of Semaglutide

The first post-baseline blood was sampled 20 minutes after oral administration and, at that point in time, the DehydraTECH GLP-1 blood semaglutide level was ~261% higher than that of the Control, demonstrating DehydraTECH's well-known ability to deliver drugs to the bloodstream faster. At each of the 19 blood sample time points, the DehydraTECH GLP-1 blood semaglutide levels were higher than the Control levels. The peak levels of semaglutide in blood were 43% higher in the DehydraTECH GLP-1 than in the Rybelsus® Control.

Blood Semaglutide Levels (mmol/L)



Rybelsus Control (blue) 7mg (n=7) DehydraTECH (orange) GLP-1 7mg (n=7)

24 hours after the ingestion of the single dose, the DehydraTECH GLP-1 blood semaglutide levels were approximately 44% higher than the Control levels (Note - only the first 10 hours post dosing is shown in the graph above).

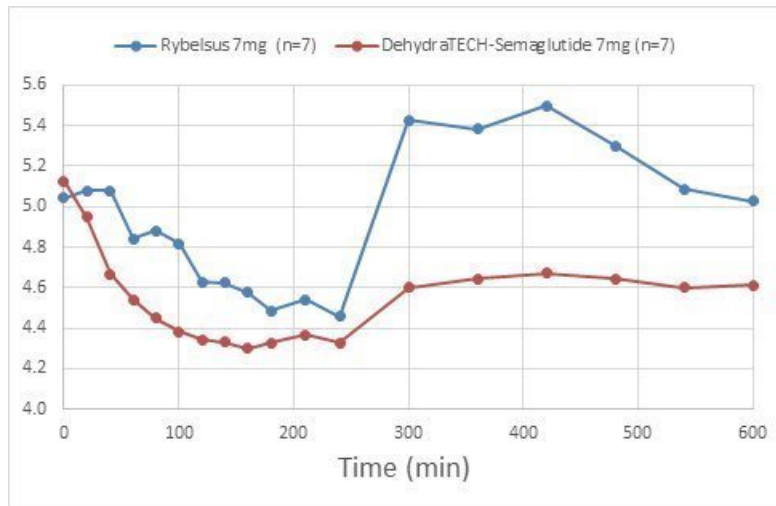
Side Effects

The DehydraTECH GLP-1 processed semaglutide was generally better tolerated than the Rybelsus® tablets themselves. Only the Rybelsus® tablets resulted in instances of moderate nausea and moderate diarrhea, whereas no such instances were reported upon DehydraTECH-semaglutide dosing.

Blood Glucose Levels

It is accepted by the Food and Drug Administration (“FDA”) that, “[one role of GLP-1](#) is to prompt the body to produce more insulin, which reduces blood glucose (sugar).” Because blood glucose levels are a key consideration in control of diabetes and other health conditions, the Study measured blood glucose levels at each of the 19 sample time points.

Blood Glucose Levels (mmol/L)



Rybelsus Control (blue) 7mg (n=7) DehydraTECH (orange) GLP-1 7mg (n=7)

The Control group evidenced inconsistent blood glucose reduction that did not prevent blood glucose spikes after eating. DehydraTECH GLP-1 reduced blood glucose to lower levels and was much more effective at maintaining consistently reduced blood glucose levels even after eating a standardized meal at the 240-minute mark and a standardized snack at the 360-minute mark. Actual data levels for each hour after Rybelsus® (control) and DehydraTECH drug administration are shown below.

Blood Glucose Levels (mmol/L)

Minutes	Control Mean	Change from Time Zero	DehydraTECH Mean	Change from Time Zero
0	5.04		5.13	
60	4.84	-3.97%	4.54	-11.42%
120	4.63	-8.22%	4.34	-15.32%
180	4.49	-11.05%	4.33	-15.60%
240	4.46	-11.61%	4.33	-15.60%
300	5.43	+7.65%	4.60	-10.31%
360	5.39	+6.80%	4.64	-9.47%
420	5.5	+9.07%	4.67	-8.91%
480	5.3	+5.10%	4.64	-9.47%
540	5.09	+0.85%	4.60	-10.31%
600	5.03	-0.28%	4.61	-10.03%
24-Hour	5.04	0.00%	4.87	-5.01%

Notably, even as long as 24 hours after dose administration, the blood glucose levels were reduced in the DehydraTECH GLP-1 group by 5.01% relative to baseline while the blood glucose levels evidenced in the Rybelsus® Control group were unchanged. Our current assumption is that the improved delivery of semaglutide using DehydraTECH is most likely responsible for the observed greater efficacy in achieving sustained blood glucose reduction, thereby helping to attenuate the postprandial spikes in blood glucose experienced in the Control group.

This Study is only meant to provide early-stage indicative information to Lexaria about the possibility of enhancing the pharmacokinetic and pharmacodynamic performance of orally delivered GLP-1 drugs to assist in guiding the Lexaria team in additional investigations. There was minor variability in the diets of the subjects at the 240-minute meal and 360-minute snack intervals noted above during the concentrated 10-hour post dosing monitoring period which could account for some of the differences in the test data, although meal and snack selection allowance was from a set of standardized choices.

Future Work

Due to the success of the Study, Lexaria is already preparing for other human and animal studies to continue the evaluation of DehydraTECH's effectiveness with GLP-1 drugs. This work will be conducted on an expedited basis given the urgent need for effective oral delivery of GLP-1 drugs and DehydraTECH's apparent ability to improve their performance. Lexaria will provide more details about its GLP-1 strategy in separate news.

About the Study

The Study was performed to provide an early-stage indication of whether DehydraTECH processing could improve *oral* drug delivery characteristics of the GLP-1 drug semaglutide sold as Rybelsus®. A single semaglutide dose of 7 mg of the Control was compared to the matching dose of the DehydraTECH GLP-1, swallowed by each subject after an overnight fasting period together with a 50 mL glass of water. The DehydraTECH GLP-1 formulation used in this Study was compound formulated strictly for research purposes. Seven healthy subjects were dosed with each test article following a cross over study design across two study visits.

About Semaglutide

Rybelsus® (semaglutide) is [the only GLP-1 drug approved by the FDA for oral dosing](#) to treat diabetes and weight loss. The FDA has also approved semaglutide marketed as Ozempic® and Wegovy®, *administered by injection*, to treat diabetes and weight loss. All three of these drugs are owned and manufactured by Novo Nordisk®.

About Lexaria Bioscience Corp.

Lexaria Bioscience Corp.'s patented drug delivery technology, DehydraTECH™, improves the way active pharmaceutical ingredients (APIs) enter the bloodstream through oral delivery. Since 2016, DehydraTECH has repeatedly demonstrated the ability to increase bio-absorption with cannabinoids, antiviral drugs, PDE5 inhibitors 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 38 patents granted and many 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 to 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. The Company provides links to third-party websites only as a courtesy to readers and disclaims any responsibility for the thoroughness, accuracy or timeliness of information at third-party websites. 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 or links to third-party websites contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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