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January 28, 2025
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Lexaria Bioscience Corp. (LEXX: NASDAQ)

LEXX: IRB Approval Clears Way for GLP-1 Study #5

Our valuation methodology employs a DCF model and a 15% discount rate. The model applies a weighted average 13% probability of ultimate approval and commercialization of products employing DehydraTECH. The model includes contributions from the United States and Rest of World.

Current Price (1/27/2025)	1.73
Valuation	**$8.00**

OUTLOOK

Lexaria is a biotechnology company seeking to enhance the bioavailability of multiple drug agents using DehydraTECH (DHT), its technology using oral and topical delivery. It combines lipophilic APIs with specific fatty acid and carrier compounds followed by dehydration.

DHT offers several attractive features: substantial improvement in bioabsorption in terms of time to measurable plasma levels & AUC, brain permeation, taste masking & side effect reduction. As DHT does not employ a covalent bond, it is not considered a new molecular entity and can rely on an API's previously conducted safety and efficacy data to obtain regulatory approval.

Lexaria receives revenues from licensing & product sales which can in part fund R&D operations. R&D activities are pursuing both preclinical and clinical programs. The lead program is investigating GLP-1 agonists for weight loss and diabetes. Other DHT candidates include antivirals, CBD, nicotine, PDE5 inhibitors, NSAIDS, hormones, colchicine & others.

We forecast penetration into global markets for weight loss, diabetes, hypertension, nicotine delivery and antiviral product categories.

SUMMARY DATA

52-Week High	**6.85**
52-Week Low	**1.42**
One-Year Return (%)	**21.8**
Beta	**1.1**
Average Daily Volume (sh)	**202,066**
Shares Outstanding (mil)	**17.6**
Market Capitalization ($mil)	**30.4**
Short Interest Ratio (days)	**2.3**
Institutional Ownership (%)	**6.1**
Insider Ownership (%)	**7.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2024	$0.1 A	$0.1 A	$0.0 A	$0.1 A	$0.5 A
2025	$0.2 A	$0.2 E	$0.2 E	$0.2 E	$0.7 E
2026					$1.2 E
2027					$1.4 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2024	-$0.13 A	-$0.06 A	-$0.13 A	-$0.14 A	-$0.47 A
2025	-$0.16 A	-$0.14 E	-$0.14 E	-$0.13 E	-$0.57 E
2026					-$0.45 E
2027					-$0.38 E

WHAT'S NEW

Lexaria Bioscience Corporation (NASDAQ: LEXX) reported fiscal first quarter 2025 results along with program updates, progress in its GLP-1 trials, a capital raise and final preparations for the Phase Ib trial evaluating DehydraTECH in obese patients. Several new patents were granted bringing the corporate total to 43.

Lexaria's primary focus for fiscal 2024 was to demonstrate that DehydraTECH (DHT) can be an effective delivery system serving the burgeoning GLP-1 agonist space. Oral options for GLP-1s are limited and initial data for DHT-GLP-1s promising, leading to the development of a series of studies that seek to find the best approach for a more convenient delivery method of this class of medicine. GLP-1 agonists can address obesity, diabetes, sleep apnea and potentially other cardiovascular, neurodegenerative and inflammatory conditions. As a result, Lexaria is evaluating three of the most important GLP-1 agonist drugs in the market, semaglutide, liraglutide and tirzepatide. Goldman Sachs and JP Morgan analysts estimate that sales from this class of drug could exceed $100 billion by 2030. While demand for these medicines is high, only one oral formulation of the drug is available, with bioavailability less than 1% of the infused formulation. Increased convenience, improved dosing regimens and lower cost to the patient can be achieved with an oral formulation if the bioavailability hurdle can be cleared.

So far, Lexaria has been able to achieve impressive bioavailability and reach therapeutic drug levels in the blood plasma faster while reducing side effects using DehydraTECH formulations of the leading GLP-1 agonists compared with their approved infused formulations. With sponsors seeking the next generation of weight loss products and opportunities for life cycle management, Lexaria's DehydraTECH formulations provide an answer. As the company continues its third and fourth human study in the class and prepares to launch its fifth, management is reaching out to potential partners who may be interested in further analysis and licensing opportunities.

First Quarter 2025 Results

Lexaria filed its quarterly results for the three-month period ending November 30, 2024. The company reported revenues of $184,000, and total operating expense of $2.9 million resulting in net loss of ($2.7) million or ($0.16) per diluted common share.

For the quarter ending November 30th, 2024 and versus the comparable prior year period:[1]

- Revenue totaled $184,000, up 22% from $151,000 as increases in licensing revenues and business to business sales were offset by a fall to zero from $900 for R&D revenues. The rise in licensing revenues was due to an increase in minimum fees earned from the licensing agreement with Premier;
- Research and development expenses totaled $2.0 million, up 240% from $0.6 million as a result of increased expenses related to the Phase Ib GLP-1 agonist trial;
- General and administrative expenses totaled $0.9 million up 29% from $0.7 million due primarily to an increase in consulting fees, salaries, advertising and promotion, partially offset by lower legal and professional fees due to fewer patent filings and less use of legal advisory and accounting services;
- Interest income was $11 vs. $7,300;
- Other loss of ($15,900) represented unrealized loss on marketable securities related to decreases in fair value;
- Net loss was ($2.7) million, or ($0.16) per share, compared to net loss of ($1.2) million or ($0.13) per share.

As of November 30th, 2024, cash and marketable securities totaled $8.1 million which compares to $6.6 million at the end of fiscal year 2024. Cash burn for 1Q:25 was approximately ($2.8) million. Cash from financing totaled $4.3 million from equity sales. Management estimates that the company holds sufficient cash to meet its financial obligations until at least November of 2025.

[1] Our year over year comparison uses originally reported data.

DehydraTECH GLP-1 Agonist Studies

Lexaria is conducting numerous GLP-1 agonist studies from *in vitro* molecular characterization studies to a Phase Ib 12-week chronic study. We summarize the latest updates on each of these efforts. For reference, see the exhibit below.

Exhibit I – GLP-1 Agonist Studies

Source: Lexaria November 2024 Corporate Presentation

Second GLP-1 Human Pilot Study

An August 27th announcement provided the first results from Lexaria's second GLP-1 Human Pilot Study designated GLP-1-H24-2. This study evaluated whether there would be a difference in blood plasma levels for subjects under fed and fasted conditions.[2] A previous study, GLP-1-H24-1, evaluated the performance of various arms under fasted conditions and found higher semaglutide blood levels for the DHT formulation. The data examining subjects in a fed condition found that there was an average of 18.8% greater drug level in the blood over the 19 observations generated. Furthermore, in only one observation at 120 minutes was the blood concentration of Rybelsus higher than DHT Rybelsus. The DHT formulation also achieved greater blood concentration much earlier than the Rybelsus group. Determining safety and tolerability of DHT-semaglutide is the primary endpoint.

[2] Novo Nordisk, the owner and manufacturer of Rybelsus, recommends taking Rybelsus on an empty stomach. Studies have shown that Rybelsus administration under fed conditions leads to decreased systemic absorption.

Exhibit II – Semaglutide Absorption (nmol/L), GLP-1-H24-2

Source: Lexaria Press Release August 27, 2024

As is Lexaria's custom, a few days after the first round of data for the GLP-1-H24-2 study, another round came out that provided the initial safety profile for DHT Rybelsus. No adverse events were observed in the DHT-Rybelsus arm while six of nine participants in the Rybelsus arm did report mild adverse events for Pilot Study #2. Lexaria compiled an exhibit that summarized the adverse events from both pilot studies which we include below.

Exhibit III – Adverse Events from Both Pilot Studies, GLP-1-H24-1, GLP-1-H24-2

Source: Lexaria Press Release August 27, 2024

Along with the oral, swallowable formulations used, Lexaria tested an in-mouth dissolvable tablet which was also tested across 18 blood draws. The average blood concentration level of the DHT-Rybelsus mouth melt was 1.27 nmol/L vs. 3.93 for the Rybelsus tablet. Dissolvable tablets may provide an alternative method of delivery.

Third GLP-1 Human Pilot Study

As part of its series of animal and human studies evaluating the use of GLP-1 agonists formulated with DehydraTECH, Lexaria ran a third human pilot study with ten healthy human volunteers. Subjects were administered a single dose of DHT-tirzepatide, compounded from Eli Lilly's Zepbound and manufactured into capsules. Study endpoints include tolerability, pharmacokinetics and blood sugar. The trial will evaluate DHT effectiveness in combination with a dual action GLP-1 agonist and a glucose-dependent insulinotropic peptide (GIP) drug absent the SNAC formulation used in the Rybelsus semaglutide composition from the first two human pilot studies.

A September 27th press release announced independent review board (IRB) approval to begin the study with dosing announced in early October. By late November, the study completed dosing of nine healthy volunteers. Subjects were initially given either a seven-day regimen of oral DehydraTECH-processed tirzepatide capsules or a single injected tirzepatide dose. During the second dosing phase, all subjects received the alternate treatment arm intervention so that each subject received both treatments. No serious adverse events were observed. Partial results from

the study were presented in a January 14th press release that highlighted the reduced level of adverse events in the DHT-tirzepatide vs. Zepbound arms. Blood glucose reduction and insulin secretion levels from the two arms were comparable. There were 38 adverse events in the Zepbound group and 20 adverse events in the DHT-tirzepatide group. With respect to gastrointestinal related adverse events, the Zepbound group experienced 22 adverse events while the DHT-tirzepatide group only registered 10. Blood glucose and insulin levels at the beginning and end of the study are provided below.

Exhibit IV – GLP-1-H24-3 Results

Compiled by Zacks Analyst

Phase Ib DehydraTECH GLP-1 Agonist Study (Fourth Study)

Following investigational new drug (IND) submission and clearance early in the year, Lexaria's Phase Ib DHT GLP-1 study in diabetes and weight loss received ethics board approval in November. A press release detailed the milestone that is required before the trial can dose the first subject. In addition to the nod by the board, clinical test article manufacturing for all planned study arms has been completed including the production of the four planned DehydraTECH formulation study arms and clinical repackaging of the commercially available Rybelsus comparator tablets for the control arms. On December 19th, Lexaria announced that dosing had begun.

Arms of the trial include:

- Arm 1 – DehydraTECH-CBD capsules
- Arm 2 – DehydraTECH-semaglutide capsules
- Arm 3 – DehydraTECH-semaglutide combined with DehydraTECH-CBD capsules
- Arm 4 – Rybelsus tablets (positive control)
- Arm 5 – DehydraTECH-tirzepatide capsules (optional arm with offset start date)

Exhibit V – Phase I Human 12-Week Study Design

Source: Lexaria Biosciences November 2024 corporate presentation

The Phase Ib is expected to enroll subjects at seven clinical investigational sites in Australia within Australian clinical regulatory authority regulations. Human Research Ethics Committee (HREC) approval was received earlier in 2024 for the primary clinical site, while clinical trial notification acknowledgement by the Australian Therapeutic Goods Administration and HREC approvals for the remaining clinical sites remain to be completed. Quality control release testing of the clinical test articles also remains to be done. Upon completion, the Phase Ib study is expected to be recognized by the FDA.

Listed under NCT06648031 on the NIH's clinical trials website, the Phase Ib DehydraTECH GLP-1 agonist study plans to enroll 20 overweight, obese, pre- or type 2 diabetic patients for each of the study arms one through four. DHT-tirzepatide Study arm #5 is expected to be added based on positive results from Lexaria's separate ongoing study GLP-1-H24-3. All drugs will be administered daily by oral tablet or capsule. No drug injections will be administered. Seven sites in Australia have been identified for the study.

Lexaria's goals for the trial are to answer several questions regarding the safety, relative performance of the different arms of the trial, whether or not DHT processing enhances the goals of weight reduction and blood sugar control and do DHT formulations administered daily reduce side effects over the trial observation period.

Human DehydraTECH-Liraglutide Study (Fifth Study)

Lexaria received independent review board (IRB) approval in January, clearing the way to begin its Human GLP-1 Study #5 (GLP-1-H25-5). It will compare an oral version of liraglutide (Saxenda) formulated from the DehydraTECH-processing of liraglutide (DHT-liraglutide) to the conventional injected liraglutide. This study was instigated by the successful results in the liraglutide 12-week rodent study which read out in November 2024. DHT-liraglutide reduced weight and blood sugar at levels exceeding the performance of comparator Rybelsus. Study #5 is expected to be conducted with 8-10 healthy volunteers to demonstrate safety and pharmacokinetic performance in humans. If results are positive, it could support the advancement of oral DHT-liraglutide to a Phase I trial.

Exhibit VI – Human Pilot Study #5 Design (GLP-1-H25-5)

Source: Lexaria Biosciences January 2025 Corporate Presentation

Exhibit VII – GLP-1 Agonist R&D Program Timeline

Source: Lexaria Biosciences January 2025 Corporate Presentation

Long Term Stability Testing
Lexaria will evaluate the chemical and microbiological purity and stability of select DHT compositions over a period of 6 to 12 months. Long-term stability is a necessary feature if the DHT-formulations are to be commercially successful and replace injectable versions of GLP-1 agonists.

New Advisory Board

Dr. Michael Gibson was appointed the Chief Medical Advisor at Lexaria to help navigate the company's newly formed Scientific Advisory Board (SAB) and advance Lexaria's multiple initiatives. He will guide the company's scientific endeavors along with Lexaria's Chief Scientific Officer, John Docherty, Dr. Karen Aust, and Dr. Philip Ainslie.

Dr. Gibson has experience running clinical trials that have led to drug and device approvals which will provide an experienced hand as Lexaria sails into new waters and more advanced trials. Dr. Aust has a Ph.D. in molecular Pharmacology from Stanford and has experience in regulatory strategy, 505(b)(2) programs in particular. The SAB also includes Dr. Ainslie who co-directs the Centre of Heart, Lung and Vascular Health at the University of British Columbia and is an expert in vascular function. Dr. Ainslie has previously consulted with Lexaria.

Appointment of New Chief Financial Officer

Lexaria announced a new Chief Financial Officer (CFO), Michael Shankman, in an October 1 press release. He replaces Nelson Cabatuan in the role. Mr. Shankman has previously worked with Lexaria and assisted with its financial reporting and 2023 audit as a designated contractor. From 2021 to 2024 Mr. Shankman provided outsourced CFO and Controller services for a national service provider, gaining extensive experience and familiarity with both public and private companies in a wide variety of industry fields. Previously, Mr. Shankman held financial leadership positions with increasing responsibility in a variety of industries, including biotechnology, medical devices, and software as service.

Material Transfer Agreement (MTA)

On September 3rd, 2024 Lexaria announced its entry into a Material Transfer Agreement (MTA) with an undisclosed pharmaceutical company. Details about the arrangement were sparse on account of the partner desiring to remain anonymous until the safety and pharmacokinetic (PK) profiles are confirmed. The goal of the arrangement is to use DehydraTECH to improve the side effect profile and PK for a product that is already on the market. Lexaria will provide the partner a temporary exclusive license to evaluate certain DehydraTECH concepts and formulations. Lexaria has delivered DHT-prepared product to the sponsor. The MTA-related work should be complete by the March 2025 timeframe. If it is successful, the arrangement may advance to the next stage where upfront, milestone and royalty payments may be part of the deal.

Pipeline

Exhibit VIII – DehydraTECH Pipeline

Source: Lexaria Biosciences January 2025 Presentation

Milestones

- Start human Pilot Study #2 (GLP-1) – May 2024
- Start human Pilot Study #3 (GLP-1) – July 2024
- Chronic Human Dosing Study (GLP-1) – 3Q:24
- Animal study interim results – mid-2024
- Human Pilot Study #2 results – September 2024
- Human Pilot Study #3 results – Late 2024
- Animal study final results – November 2024
- Chronic dosing human study results – December 2024
- Launch of Phase Ib DHT-GLP-1 Diabetes/Weight Loss Study – November 2024
- Completion of testing by global pharmaceutical company (MTA) – March 2025
- Results from long term stability and mode of action characterization - 2025
- DHT-CBD hypertension study – 2H:25

Capital Raises

On October 16, 2024, Lexaria issued 1,633,987 shares of common stock at $3.06 per share for gross and net proceeds of $5.0 million and $4.5 million. Along with the issuance of common stock, Lexaria issued 4,551,019 share purchase warrants, which consisted of 1,633,987 warrants directly tied to the capital raise and another 2,917,032 warrants that were repriced from $4.75 to $3.06. The latter warrants were issued along with the April 30, 2024 financing. 57,190 placement agent warrants were also issued at an exercise price of $3.825 per share. In October 2024, Lexaria sold 8,402 shares of common stock through an At the Market (ATM) offering for gross proceeds of $26,146.

Summary

As Lexaria reports its first quarter for fiscal year 2025, we bring investors up to date on progress with the GLP-1 agonist trials. Study #4 is adding a fifth arm to measure DHT-tirzepatide in an oral capsule to measure safety and the impact of the drug on glucose and diabetes in Type 2 diabetes patients. The IRB cleared Study #5 to start. The study will examine liraglutide in its approved form (Saxenda) in comparison with a DHT formulated version in healthy volunteers. In addition to advances in trial work, the company adds some new faces including Michael Shankman as CFO as well as SAB board members Drs. Gibson, Aust and Ainslie who bring regulatory and development experience to Lexaria's scientific endeavors.

As Lexaria evolves into its next iteration focused on execution of the programs it has incubated over the last several years, The recent MTA signed with a pharmaceutical company is further evidence of the commercial potential of the DehydraTECH platform. We expect to hear news on next steps for this partnership in the next few months. If the partner elects to move forward, this could provide upfront, milestone and royalty cash flows to Lexaria which can further support internal research and development efforts. We maintain our valuation of $8.00 per share.

PROJECTED FINANCIALS

Lexaria Bioscience Corp. - Income Statement

HISTORICAL STOCK PRICE

Lexaria Bioscience Corp. – Share Price Chart[3]

[3] Source: Zacks Research System

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