Zacks Small-Cap Research
*Sponsored – Impartial – Comprehensive*

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# Lexaria Bioscience Corp. (LEXX: NASDAQ)

## *LEXX: GLP-1s' Sweet Opportunity*

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 (11/29/2023) | $1.50 |
| **Valuation** | **$10.00** |

## 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, DHT is not a new molecular entity and can rely on 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 CBD for the reduction of hypertension with four clinical trials conducted. Other DHT candidates include antivirals, nicotine, PDE5 inhibitors, NSAIDS, hormones, colchicine & others.

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

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **3.60** |
| **52-Week Low** | **0.65** |
| **One-Year Return (%)** | **-44.4** |
| **Beta** | **0.9** |
| **Average Daily Volume (sh)** | **110,480** |
| **Shares Outstanding (mil)** | **10.3** |
| **Market Capitalization ($mil)** | **15.5** |
| **Short Interest Ratio (days)** | **4.3** |
| **Institutional Ownership (%)** | **8.4** |
| **Insider Ownership (%)** | **13.6** |
| **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 2023 Estimate** | **N/A** |
| **P/E using 2024 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Drugs** |

## ZACKS ESTIMATES

### Revenue

(In millions of USD)

| | Q1 (Nov) | Q2 (Feb) | Q3 (May) | Q4 (Aug) | Year (Aug) |
|---|---|---|---|---|---|
| 2022 | $0.0 A | $0.0 A | $0.1 A | $0.1 A | $0.3 A |
| 2023 | $0.1 A | $0.0 A | $0.1 A | $0.0 A | $0.2 A |
| 2024 | | | | | $0.8 E |
| 2025 | | | | | $1.0 E |

### Earnings per Share

| | Q1 (Nov) | Q2 (Feb) | Q3 (May) | Q4 (Aug) | Year (Aug) |
|---|---|---|---|---|---|
| 2022 | -$0.35 A | -$0.24 A | -$0.41 A | -$0.24 A | -$1.24 A |
| 2023 | -$0.30 A | -$0.22 A | -$0.37 A | -$0.15 A | -$1.01 A |
| 2024 | | | | | -$0.60 E |
| 2025 | | | | | -$0.51 E |

## WHAT'S NEW

Lexaria Bioscience Corporation (NASDAQ: LEXX) reports fiscal full year 2023 results along with program updates, new deals and a small capital raise since the third quarter report in August. The company announced that the investigational new drug (IND) application would be delayed on account of a supplier. It expanded its GLP-1 agonist research and provided preliminary data from the related studies and announced the grant of two Canadian patents. We expect upfront and other revenues in FY:24 from the announced SulfoSyn license which applies Lexaria's technology to a supplement to improve bioavailability and stability.

**FY:23 Results**

Lexaria filed its fiscal year 2023 Form 10-K on November 20, 2023. The company reported FY:23 revenues of $226,000, and total operating expense of $6.7 million resulting in net loss of ($6.7) million or ($1.01) per basic and diluted common share.

For the fiscal year ending August 31, 2023 and versus the comparable prior period in 2022:[1]

- Revenue totaled $226,000, down 11% from $255,000 on a decrease in Product and Other revenues. These amounts were offset by an increase in intellectual property licensing. Some of the year over year decline was attributable to reclassifications required by the new auditor;
- Gross profit increased to $195 from $184 on account of the shift to licensing revenues and away from product revenues;
- Research and development expenses totaled $3.7 million, up 99% from $1.8 million tied to the multiple DehydraTECH investigational research programs underway, including analysis and execution of the hypertension, nicotine and diabetes studies;
- General and administrative expenses totaled $3.1 million, down by almost half from $5.7 million due primarily to a decrease in consulting fees, salary and stock-based compensation. Legal fees, advertising and promotion, and investor relations spending were also lower. Lexaria altered its accounting methodology and excludes changes in value for marketable securities from the general and administrative line which comprised part of the year over year decline in this line item;
- Other income included interest on cash balances of $43,000 offset by unrealized losses on marketable securities of ($222,000);
- Net loss was ($6.7) million, or ($1.01) per share, compared to net loss of ($7.3) million or ($1.24) per share.

As of August 31, 2023, cash and marketable securities totaled $1.5 million which compares to $6.2 million at the end of fiscal year 2022. Cash burn for FY:23 was approximately ($6.1) million. Following the end of the reporting period, Lexaria raised a net $1.3 million.

**SulfoSyn License Agreement**

In mid-October, Lexaria announced an exclusive global collaboration and license agreement with SulfoSyn Limited. SulfoSyn lacks any detailed information or a website, but we speculate that it might be associated with an anti-aging-focused life sciences company. Lexaria confirms that the parent company does have a marketed product. We have not been able to confirm the identity of the ultimate owner of SulfoSyn, but it is very likely that SulfoSyn will share the licensed technology with a recognized entity or brand when and if it reaches commercialization stage. The license allows for non-pharmaceutical use of DehydraTECH with sulforaphane, which may be used in supplements, additives, foods and dietary ingredients among other products. An upfront cash payment was made and minimum future payments are in place. Royalties may also be paid if in excess of minimum contractual payments. Lexaria will also perform certain manufacturing services for SulfoSyn in the United States for two years in its Atlanta facility. While a firm order has not yet been placed, we anticipate this will occur in the near term.

Sulforaphane is a chemical compound that is found in a variety of cruciferous vegetables such as cabbage, cauliflower, brussels sprouts and broccoli among others. It is considered an antioxidant and anti-inflammatory that may provide health benefits. It may reduce risks related to cancer and promote cardiovascular and nervous system

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

health. Sulforaphane may also enhance detoxification through activation of enzymes. Sulforaphane tablets are available but offer low bioavailability as is the case with many supplements. The shelf stability of the compound is also very limited as it degrades quickly. After a few days unstabilized sulforaphane degrades 80% or more. Using DehydraTECH to stabilize and deliver this supplement may provide substantial improvement in utility and potentially improve sales of this nutritional supplement.

**CPG Product Subsidiary**

In July, Lexaria incorporated a new wholly-owned subsidiary called Lexaria Nutraceutical Corp. in order to optimize its DehydraTECH strategy that serves a number of markets that fall under different regulatory regimes worldwide. The strategy enables Lexaria to more efficiently participate in M&A activity. The subsidiary, which is referred to as LEXX Nutra, has received a perpetual license to create consumer packaged goods and intermediate ingredients for any molecule save those associated with nicotine or cannabis. The subsidiary is also prevented from using the license to produce a pharmaceutical product. The parent also made modifications to other subsidiaries' arrangements, amending the exclusive licensing rights of Lexaria Pharmaceutical Corp. to only pertain to the manufacture or licensing of pharmaceutical products, excluding nicotine.

**Capital Raise**

On September 29th, Lexaria announced a $1.6 million registered direct offering with a private investor. On October 3rd, the deal was closed with 1.6 million units sold, which included a share of stock or a pre-funded warrant along with a warrant with a $0.97 exercise price. Net proceeds of $1.29 million were received. As of mid-November, all pre-funded warrants were exercised.

**Patents**

New patents were issued during 2023 with announcements made in April and June that highlighted several grants around the globe. In July, a nicotine patent was issued related to sublingual delivery using DehydraTECH. October brought two more Canadian patents into the fold for beverage and tobacco applications.

2023 Issued Patents:

- Canada
  - Food and Beverage Compositions Infused with Lipophilic Active Agents and Methods of Use Thereof
  - Compositions Infused with Nicotine Compounds and Methods of Use Thereof
  - Stable Ready-to-drink Beverage Compositions Comprising Lipophilic Active Agents
  - Lipophilic Active Agent Infused Tobacco Leaves and/or Tobacco Materials and Methods of Use Thereof
- US
  - Pharmaceutical Compositions and Methods for Treating Hypertension
  - Compositions and Methods for Treating Hypertension
  - Compositions and Methods For Sublingual Delivery of Nicotine
    - Patent #11,700,875
    - Progressing through other jurisdictions outside of the US
- Japan
  - Stable Ready-to-Drink Beverage Compositions Comprising Lipophilic Active Agents
- Australia
  - Compositions and Methods for Enhanced Delivery of Antiviral Agents.

Over the last several months, multiple jurisdictions have issued new patents to Lexaria including Japan (1), Australia (1), Canada (4) and the US (3). The US patents protect the use of DehydraTECH enhanced cannabidiol for use in pharmaceutical compositions and methods for treating hypertension and DehydraTECH enhanced cannabidiol for use in general compositions and methods for treating hypertension.

**Exhibit I – DehydraTECH Patented Manufacturing Process[2]**


## Hypertension Study Details

Lexaria has completed four human hypertension studies that evaluated the use of DHT-CBD in reducing blood pressure. The first human study enrolled 24 subjects and examined diastolic pressure over a three-hour period and found that the pressure was lower in those administered DHT-CBD. The second study was conducted in 16 volunteers and confirmed that DHT can reduce arterial stiffness. The fourth study began in early April 2022, enrolled 66 subjects and has reported several data sets.

**Exhibit II – Summary of DehydraTECH CBD Studies for Hypertension[3]**

| Study | Type | Report Date | Detail | Location | Dose |
|---|---|---|---|---|---|
| HYPER-A21-1 | Animal | May-21 | Absorption rate, speed & tolerability | USA | |
| HYPER-A21-2 | Animal | May-21 | Absorption rate, speed & tolerability | USA | |
| HYPER-H21-1 | Human | Jul-21 | 24 subject BP & heart rate analysis, PK | Europe | 1x300 mg/day |
| HYPER-H21-2 | Human | Sep-21 | 16 subject BP & heart rate analysis, other | Europe | 3x150 mg/day |
| HYPER-H21-3 | Human | Apr-22 | 16 subject stress test, acute pulmonary HTN | Europe | 1x300 mg/day |
| HYPER-H21-4 | Human | Oct-22 | 66 subject RCT w/ placebo control | Europe | 3/150 mg/day |

Other milestones for the hypertension program include the anticipated IND submission and additional preparations for the clinical trial. If the IND is cleared by the FDA, we then expect the start of a Phase Ib study. In late August, Lexaria announced that work that was under its control related to the IND filing had been completed. However, other documentation required from Lexaria's service providers had been delayed. We expect to hear an update soon on the status of the IND preparation.

## Nicotine Updates

In May, Lexaria reported that dosing of the 36 patients was completed for its human nicotine study (NIC-H22-1) and in early August provided another update summarizing topline results. Results from the study demonstrated a statistically significant difference between Tmax for the DehydraTECH nicotine pouch and both comparable arms. Time to Tmax of 15.37 minutes was 2.3 minutes faster than what was produced in the on! arm and 3.1 minutes faster than the time measured in the ZYM arm. In percentage terms, this represented a 15% and 20% faster response to achieve maximum blood saturation levels.

**Exhibit III – Time to Tmax[4]**

| Nicotine Product | p-value | Tmax (minutes) |
|---|---|---|
| DehydraTech | | 15.37 |
| on! | 0.004 | 17.67 |
| ZYN | 0.000 | 18.48 |

[2] Lexaria Biosciences November 2023 corporate presentation.
[3] Source: Company press releases and Zacks analyst compilation
[4] Compiled by Zacks' analyst using company provided data.

Lexaria cited a pharmacokinetic (PK) study that quantified the time required for Tmax to be reached with a combustible cigarette at 8 minutes. Relative to this benchmark, the company put together a comparison of other nicotine delivery methods including the data generated from the NIC-H22-1 study. Of the eight comparable vehicles, DehydraTECH oral pouch was the fastest to Tmax relative to combustible cigarettes.

**Exhibit IV – Time to Tmax for Various Nicotine Delivery Mechanisms[5]**

| Nicotine Product | Tmax (minutes) | Percent Time Delay |
|---|---|---|
| Combustible cigarette | 8.00 | baseline |
| on! oral pouch | 17.67 | 121% |
| Nasal spray | up to 18 | up to 125% |
| ZYN oral pouch | 18.48 | 131% |
| Subcutaneous injection | 25.00 | 213% |
| Gum | 30.00 | 275% |
| Lozenge | 60.00 | 650% |
| Oral solution | 66.00 | 725% |
| **DehydraTech oral pouch** | **15.37** | **92%** |

Another component of the study examined qualitative aspects of the DehydraTECH nicotine pouch that were determined with a patient survey. Six different categories were reported, examining both the desirable and undesirable attributes of nicotine consumption.

- Euphoria and Head Rush: The highest percentage of users reporting that they felt euphoric at all time points were the Lexaria users; and the highest percentage of users reporting they felt a head rush at the 5 and 30-minute marks were also Lexaria users;
- Tolerability: The highest endorsement score for users reporting "I tolerated this product well" were the Lexaria users, with statistical significance demonstrated at the second dosing visit in particular (p=0.007);
- Pleasure: The highest percentage of users reporting that they considered the experience "pleasurable" at the 30-minute mark were the Lexaria users, while the on! users reported the lowest percentage as "pleasurable" at this point;
- Mouth and Throat-burn: Lexaria scored best for percent enjoyment of the nicotine induced burning sensation in the mouth and throat. The highest percentage of severe mouth and throat-burn events were reported by users of the on! pouch;
- Nausea: The highest frequency of moderate and severe nausea effects was reported by users of the ZYN and on! pouches respectively; with the lowest frequency reported by users of the Lexaria pouch;
- Hiccups: Moderate to severe hiccups were only reported by users of the on! and ZYN products.

We anticipate that partner work with global tobacco companies will expand now that data from the study are available. Lexaria plans to share summary data to identify interest from these potential collaborators and seeks to commercialize DehydraTECH nicotine with suitable industry partners.

## DehydraTECH and Diabetes

In its ongoing effort to expand into new therapeutic areas, Lexaria launched an animal study in diabetes in November 2022 designated DIAB-A22-1. It has evaluated the DehydraTECH-processed cannabidiol (CBD) molecule and how it impacts diabetes-related biomarkers in rats. The associated press release highlighted the relationship between heart disease, hypertension and diabetes and the prevalence of diabetes, as the seventh most common cause of death. Impetus for the study has come from other work cited in the press release supporting CBD efficacy in reducing the incidence of diabetes.

Results from the diabetes study generated multiple outcomes including weight loss in obese diabetic-conditioned animals, improved triglyceride and variable cholesterol levels. These biomarkers are all associated with diabetes and improvements can be associated with better outcomes for diabetic patients. Weight loss was observed four days after initial dosing of DehydraTECH-CBD. Maximum weight loss was achieved nine days after dosing began

[5] Compiled by Zacks' analyst using data included in Lexaria press release and sourced from Nicotine Chemistry, Metabolism, Kinetics and Biomarkers.

and was maintained for the 8-week duration of the study. The weight loss averaged 7% of body weight for both of the doses used in the study (30 mg/Kg and 100 mg/Kg). Only the DehydraTECH-CBD-dosed animals weighed less at the end of the study than at the beginning, whereas the weight of the untreated obese animals trended upwards throughout. Food and water intake for all groups was similar, supporting the hypothesis that weight loss is, at least in part, attributable to enhanced metabolic function.

The strength of the data in the animal studies led Lexaria to pursue a human trial in diabetes using DehydraTECH CBD to see if any of the improvements observed in animals are exhibited in humans. Details of the effort are included in an August 2nd press release. Study design development is underway for the human study, and when complete will be submitted to an independent review board for approval. The study will take place at the same hospital in Europe that conducted the human hypertension studies with DehydraTECH. Study design is targeted to be complete by the first half of September followed by submission to the medical ethics boards for clearance.

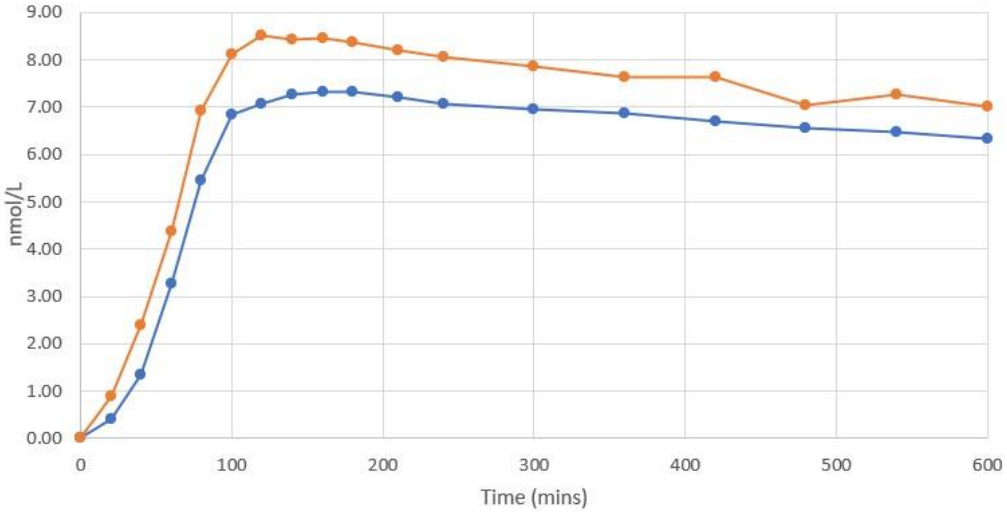
Efforts to advance diabetes and weight loss research were further advanced with the September 21, 2003 press release that announced Lexaria's intent to evaluate performance of the glucagon-like peptide-1 (GLP-1) agonist class using DehydraTECH. The goal of the efforts is to determine if employing DehydraTECH for delivery would be able to reduce side effects, enhance weight loss, improve health outcomes, improve bioavailability and reduce cost. Targeted products include Ozempic, Wegovy and Rybelsus. Another product in this class called Zepbound by Eli Lilly was recently approved by the FDA for weight loss potentially providing another candidate for Lexaria's work.

In late October, industry news regarding the effectiveness of DehydraTECH was included in an article that highlighted the drug delivery platform's ability to control blood sugar and reduce body weight. The review noted that DehydraTECH is easily integrated into oral product manufacturing processes, the GLP-1 market has the potential to be very large, DehydraTECH has broad applications and the platform has proven itself in a number of products and indications.

Lexaria provided an update in early November noting that it is expanding its diabetes study program, including using DehydraTECH with GLP-1 drugs alone and in combination with other molecules. This was followed by a pair of press releases in late November summarizing semaglutide comparative performance using Novo Nordisk's oral formulation and a DehydraTECH formulated version of semaglutide.

On November 27th, Lexaria provided an update on its semaglutide study. The press release reported that the DehydraTECH formulation of semaglutide sustained higher levels of the drug in the blood, achieved faster peak drug delivery and produced fewer side effects compared with Novo Nordisk's oral formulation Rybelsus. A university research center is conducting the study comparing 7 mg of semaglutide in a Rybelsus tablet to a compound formulated in capsule form using DehydraTECH processing technology enhancements. Rybelsus has distinguished itself with strikingly low bioavailability of 1% or less, providing an opening for an alternative that achieves better results. The exhibit below illustrates the blood plasma levels of Rybelsus and DehydraTECH semaglutide over a 10-hour period with the DehydraTECH formulation achieving higher blood levels at each measurement point.

**Exhibit V – Blood Levels of Semaglutide (Rybelsus, Blue; DehydraTECH, Orange)[6]**

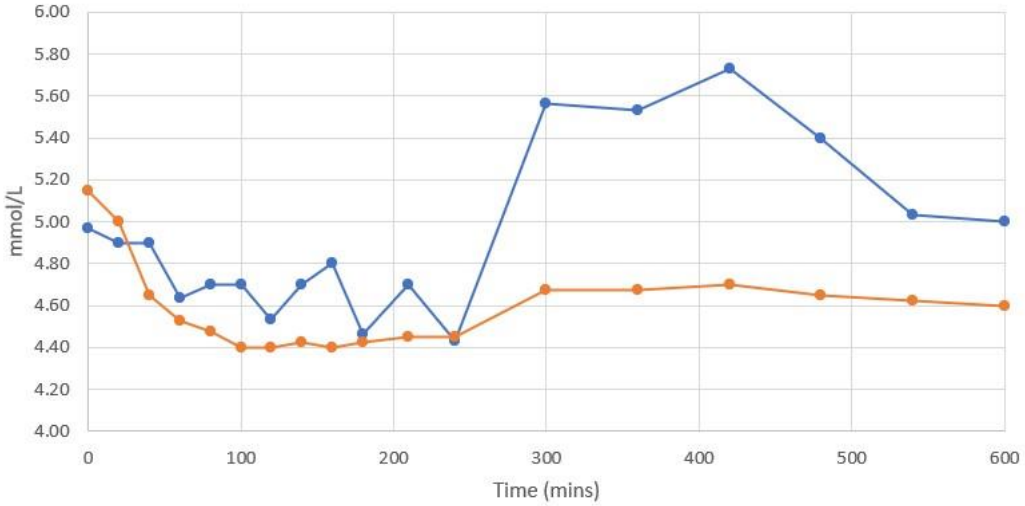



[6] Source: Lexaria Press Release, November 27, 2023. This was a small sample with only three observations for Rybelsus and four for DehydraTECH.

Two of the three control subjects and zero of the four DehydraTECH GLP-1 subjects reported experiencing moderate nausea. All three control subjects reported experiencing mild nausea at both the 2-hour and 10-hour timepoints whereas only one DehydraTECH semaglutide subject reported mild nausea and only at the single, 2-hour timepoint.

On November 28th, a follow up press release was promulgated providing additional data summarizing the effects of varying formulations of semaglutide on blood glucose. The results demonstrated lower overall blood glucose levels and less variability for the DehydraTECH semaglutide oral formulation compared with Rybelsus. The study evaluated blood glucose levels every 20 minutes for the first few hours then every hour over the measurement period. Subjects consumed a standardized meal at the 240-minute (4 hour) mark and a snack at the 360-minute (6 hour) mark.

**Exhibit VI – Blood Glucose Levels (Rybelsus, Blue; DehydraTECH, Orange)[7]**




Lexaria emphasized the small sample size for the study noting that the work is intended to guide future studies. Additional results are expected to be released in December or early January following the completion of a part two cross-over study. As is customary in a cross-over design, the control and DehydraTECH subjects will switch treatments and be dosed in reverse order compared to part one.

The semaglutide study is intended to provide pharmacokinetic and pharmacodynamic data to help guide future work. Since there were only seven subjects in the trial, there are insufficient data to provide significant results; however, as shown in the information provided, initial indications show improved performance from the DehydraTECH formulations of semaglutide.

Lexaria may further consider studying DehydraTECH in further diabetes trials to examine both blood sugar control and weight loss. The study may include combination approaches of DehydraTECH CBD with DehydraTECH semaglutide. Management has penciled in this trial to start in mid-2024 pending the availability of funding.

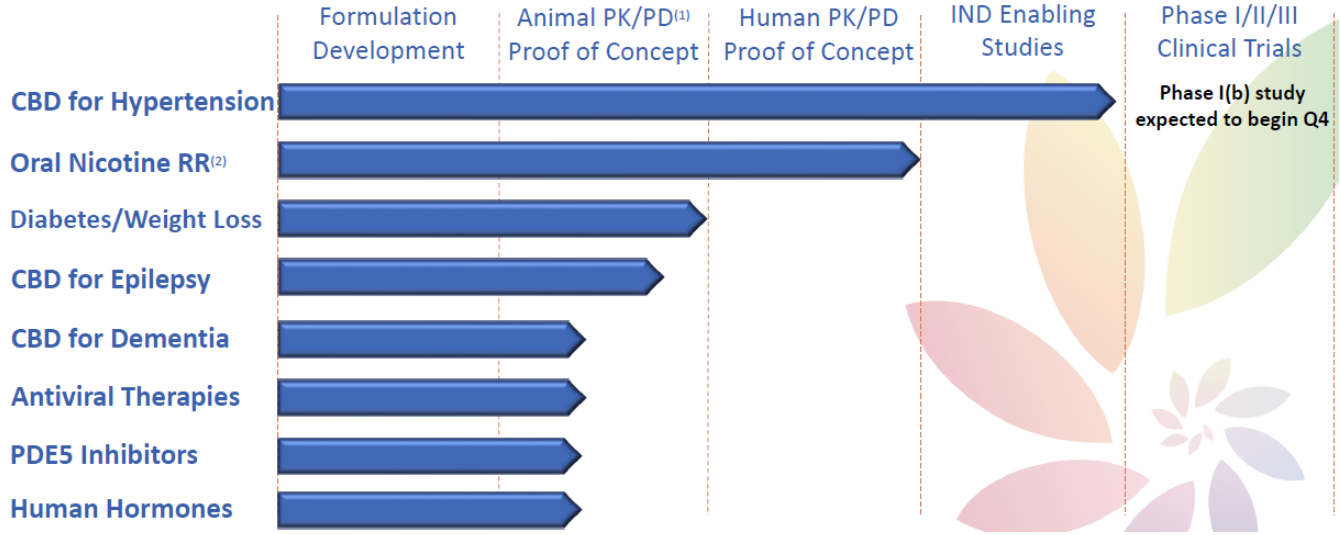
**Milestones (Calendar Quarters Used)**

- CFO Mike Shankman appointed – June 2023
- DEM-A21-1 (diabetes) study results – 4Q:23
- IND submission for DHT-CBD Phase Ib – 1Q:24
- GLP-1 combination study – 2024
- Update on objectives for GLP-1 program – 1H:24
- NIC-H22-1 (nicotine comparison with on! & ZYN) update to final results – 2024
- DHT-CBD Phase Ib hypertension study – 3Q:24

[7] Source: Lexaria Press Release, November 27, 2023. This was a small sample with only three observations for Rybelsus and four for DehydraTECH.

## Pipeline

**Exhibit VII – DehydraTECH Pipeline[8]**




### Valuation

We update our valuation to reflect the updated share balance, other claims on equity and anticipated capital needs over the balance of 2024. Our valuation is $10.00 per share.

### Summary

Lexaria has continued to generate new data for its DehydraTECH CBD product in a variety of indications. Recent highlights include the licensing arrangement with SulfoSyn which provided an upfront and anticipated revenues in 2024. Lexaria bulked up on the sweet looking opportunity with the GLP-1 agonist leader semaglutide where it launched a study evaluating bioavailability and effect on diabetes markers. A small capital raise helps extend the runway; however, more capital will be needed to advance the larger clinical work that Lexaria is planning. With many irons in the fire, we expect to see additional revenue opportunities materialize in FY:24. We update our valuation to $10.00 per share.

[8] Lexaria Biosciences November 2023 corporate presentation.

## PROJECTED FINANCIALS

**Lexaria Bioscience Corp. - Income Statement[9]**

| Lexaria Bioscience Corp. | 2022 A | Q1 A | Q2 A | Q3 A | Q4 A | 2023 A | 2024 E | 2025 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$255** | **$101** | **$35** | **$93** | **($3)** | **$226** | **$812** | **$975** |
| YOY Growth | -65% | 631% | 15% | -7% | -103% | -11% | 259% | 20% |
| Gross Profit | $184 | $86 | $32 | $80 | ($3) | $195 | $650 | $780 |
| Research & Development | $1,843 | $829 | $696 | $1,641 | $500 | $3,667 | $3,777 | $3,890 |
| General & Administrative | $5,725 | $1,025 | $647 | $823 | $567 | $3,062 | $3,184 | $3,312 |
| Income from operations | ($7,384) | ($1,769) | ($1,311) | ($2,384) | ($1,071) | ($6,534) | ($6,312) | ($6,422) |
| Non Controlling Interest | ($114) | ($13) | ($13) | ($7) | ($15) | ($48) | ($37) | ($38) |
| Pre-Tax Income | ($7,269) | ($1,756) | ($1,298) | ($2,377) | ($1,234) | ($6,665) | ($6,312) | ($6,422) |
| **Net Income** | **($7,269)** | **($1,756)** | **($1,298)** | **($2,377)** | **($1,234)** | **($6,665)** | **($6,312)** | **($6,422)** |
| *Net Margin* | *-2846%* | *-1730%* | *-3707%* | *-2551%* | *35953%* | *-2946%* | *-777%* | *-659%* |
| **Reported EPS** | **($1.24)** | **($0.30)** | **($0.22)** | **($0.37)** | **($0.15)** | **($1.01)** | **($0.60)** | **($0.51)** |
| Basic Shares Outstanding | 5,885 | 5,951 | 5,951 | 6,441 | 8,080 | 6,614 | 10,550 | 12,670 |

*Source: Company Filing // Zacks Investment Research, Inc. Estimates*

[9] 4Q:23 revenues are backed out of full year reported results and negative value reflects a reclassification of revenues over the full year. Zacks uses numbers as originally reported.

## HISTORICAL STOCK PRICE

**Lexaria Bioscience Corp. – Share Price Chart[10]**


[10] Source: Zacks Research System

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