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Lexaria Bioscience Corp. (LEXX: NASDAQ)

DehydraTECH: Developing Diabetes and Dementia

Based on our DCF model and a 15% discount rate, Lexaria is valued at approximately $15.00 per share. Our 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 (1/13/2023)	$2.77
Valuation	**$15.00**

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 completed or ongoing. 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. Our valuation assumes a 2024 regulatory approval and commercialization of DHT CBD in the US and developed markets.

SUMMARY DATA

52-Week High	**4.94**
52-Week Low	**1.80**
One-Year Return (%)	**-37.2**
Beta	**1.1**
Average Daily Volume (sh)	**13,700**
Shares Outstanding (mil)	**5.95**
Market Capitalization ($mil)	**16.5**
Short Interest Ratio (days)	**20.2**
Institutional Ownership (%)	**11.6**
Insider Ownership (%)	**17.8**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2021	$0.3 A	$0.2 A	$0.2 A	$0.0 A	$0.7 A
2022	$0.0 A	$0.0 A	$0.1 A	$0.2 E	$0.3 E
2023					$1.3 E
2024					$1.5 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2021	-$0.24 A	$0.10 A	-$0.50 A	-$0.26 A	-$0.95 A
2022	-$0.35 A	$0.25 A	-$0.41 A	-$0.21 E	-$1.21 E
2023					-$1.04 E
2024					-$0.87 E

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WHAT'S NEW

January 2023 Operational Update

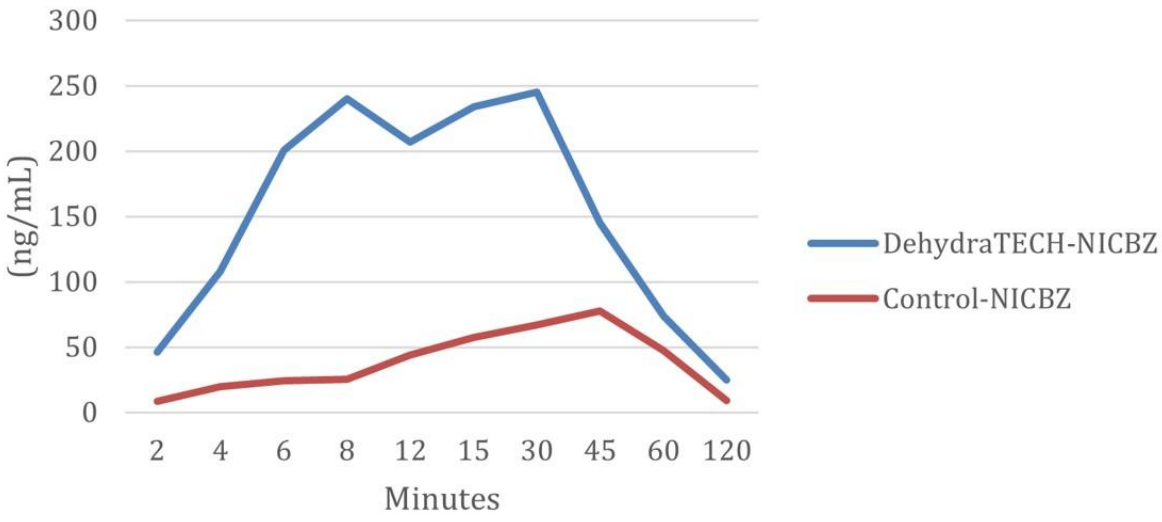
Lexaria Bioscience Corporation's (NASDAQ: LEXX) CEO, Chris Bunka, published a shareholder letter last week highlighting 2022 achievements and outlining the expected path forward for its portfolio of programs. Mr. Bunka listed capital expenditure priorities, summarized successful results from the numerous active and completed studies, emphasized ongoing partnership development activities and revealed that institutional ownership in the company had increased. The anticipated pathway forward for the DehydraTECH (DHT) cannabidiol (CBD) program that will pursue a 505(b)(2) new drug application following registrational studies was detailed. Advanced clinical work will likely be done in conjunction with a partner. The nicotine program is another valuable program in the pipeline and relatively close to commercial status. A successful result from the NIC-H22-1 trial may clear a path for a relationship with an established company. The CEO also discussed other work in seizures, diabetes and dementia that is expanded upon below.

Nicotine Updates

In an November 1st press release, Lexaria announced its receipt of Independent Review Board (IRB) approval for its human nicotine study designated NIC-H22-1. The study, which expects to enroll 36 subjects, is designed to be a randomized, double-blind, cross over study in cigarette smokers. The pharmacokinetic (PK) evaluation will dose each individual three times over a period of several weeks using an oral nicotine pouch. The pouch will be either DHT nicotine, or competing brands On! or Zyn.

Dosing for the trial began in December 2022, and will produce results that are evaluated with questionnaires and eight blood samples to evaluate nicotine delivery to the bloodstream. Other biomarkers including blood pressure and heart rate will also be taken. The goal of the study is to show whether or not DHT is able to provide better oral-tissue absorption and reduced negative experiences vs. the other participants in the study. Support for NIC-H22-1 was provided by previous animal model work demonstrating faster peak delivery of nicotine using DHT.

Exhibit I – Nicotine Bloodstream Delivery vs. Control (NIC-A21-1)[1]



[1] Source: Lexaria Press Release, November 1, 2022. Lexaria Receives Independent Review Board Approval for its Upcoming Human Oral Nicotine Study.

DehydraTECH and Diabetes

In its consistent effort to expand into new therapeutic areas, Lexaria began an animal study in diabetes which will be designated DIAB-A22-1. The effort, which started in November 2022, will evaluate the DehydraTECH-processed cannabidiol (CBD) and how it impacts diabetes 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 its efficacy in reducing the incidence of diabetes.

A dose ranging study will be conducted over 56 days that will evaluate 32 male Zucker rats. 24 of the rats will be obese and eight will be lean. The two groups will be compared with respect to weight gain, blood glucose, cholesterol and triglyceride levels between those administered DHT-CBD and those which were not. Blood will be drawn six times over the course of the study. It will be conducted in Canada and is expected to be complete in January 2023 with data available shortly thereafter.

DehydraTECH and Dementia

Dementia has been a tough nut to crack over the last several decades, with several drugs approved to treat the symptoms of the disease in the early 2000s, and a long break until the next approval in mid-2021. This drug, Biogen's Aduhelm for Alzheimer's disease (AD), suffered several setbacks both before and after it was approved and is not expected to be an important contributor due to its limited benefit and negative side effects. More recently, in early January 2023, another disease modifying therapy was approved, Leqembi, which shows slightly better results, but lacks the clear-cut benefit desired. This leaves the field wide open for therapies that can either slow or improve the symptoms of dementia, and shows that the FDA seriously considers new candidates in this space given the dearth of available therapies.

In response to this unmet need and an anticipated benefit from DehydraTECH administered CBD, Lexaria is conducting a preclinical study designated DEM-A22-1 to measure the impact in 32 Long Evans rats. The rats will be dosed with DHT CBD and will employ a novel object recognition test to measure the impact of the investigational drug on cognitive performance. Lexaria outlines further details of the study and the potential market size for drugs used in dementia in a November 10, 2023 press release.

Support for launching the study is based on the benefit DHT-CBD shows in the reduction of blood pressure. Individuals with high blood pressure are more likely to develop vascular dementia, which is the second most common dementia.[2] Research cited by Lexaria in their press release[3] finds that the endocannabinoid system is associated with many neurodegenerative diseases including Alzheimer's disease, Huntington's disease, Parkinson's disease and vascular dementia. If DEM-A22-1 is successful, further studies will be considered.

Seizure Study Program

In June 2018, the FDA approved GW Pharmaceuticals' Epidiolex, a CBD oral solution for treatment of seizures in children with Lennox-Gastaut or Dravet syndrome. This was the first drug approved that included an active ingredient from the cannabis plant. GW Pharmaceuticals was later acquired by Jazz Pharmaceuticals (NASDAQ: JAZZ) in early 2021 and has generated an estimated $750 million in revenues for 2022 and is further expected to break the billion-dollar mark by 2024.

The success of Epidiolex spurred Lexaria to perform its own studies evaluating the efficacy of CBD for seizures using its DHT delivery technology. Animal seizure study program EPIL-A21-1 was designed to evaluate whether DHT-CBD could provide similar seizure inhibiting efficacy at lower doses than those used in Epidiolex. The goal would be to achieve similar efficacy while reducing systemic exposure and related side effects with the lower dose.

In the animal study, Lexaria provided initial results in a November 29th, 2022 press release. An initial electrical stimulation pilot study in animals that examined three different doses revealed that, at the lower doses of 50 mg/kg and 75 mg/kg, DHT-CBD was more efficacious than Epidiolex in reducing or eliminating seizure activity. While Epidiolex was more efficacious than DHT-CBD in eliminating seizure activity at the highest dose tested in the pilot study of 100 mg/kg, only DHT-CBD demonstrated some reduction in seizure activity at the 50 mg/kg dose. At the 75 mg/kg dose DHT-CBD demonstrated full elimination of seizure activity in two thirds of the animals compared to

[2] Alzheimer's Society. High Blood Pressure and Dementia.
[3] Walther, S., Halpern, M. Cannabinoids and Dementia: A Review of Clinical and Preclinical Data. Pharmaceuticals. August 2010.

50% of the Epidiolex treated animals. In this regard, there was an apparent trend for DHT-CBD to work better at lower doses than Epidiolex.

Following the pilot experiment, a second electrical stimulation animal seizure study was performed where time to peak efficacy was measured at various post-dosing time points. DHT-CBD demonstrated an apparent trend toward enhanced effectiveness, in this case based on rapidity of action. After 30 minutes, 50% of the animals dosed with DHT-CBD showed partial reduction or full elimination of seizure activity whereas 100% of the Epidiolex-dosed animals were exhibiting full seizure activity at 30 minutes. After 60 minutes, 87.5% of the animals dosed with DHT-CBD showed partial reduction or full elimination of seizure activity compared to 62.5% of the Epidiolex-dosed animals showing partial reduction or full elimination of seizure activity. Epidiolex demonstrated enhanced seizure reduction capabilities at later time points in the study.

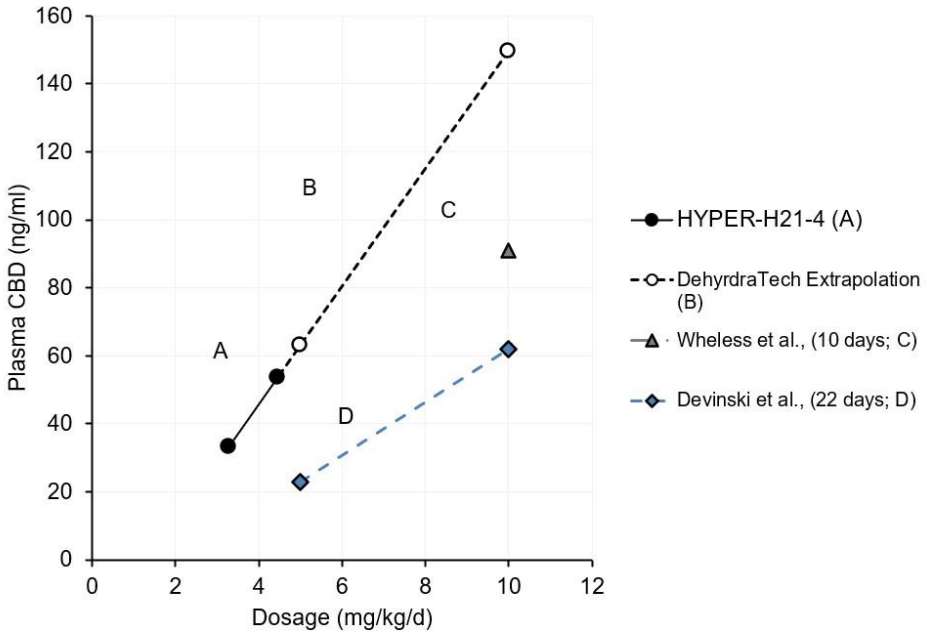
The results are supportive of further study for DHT-CBD in the clinic, providing the benefits of the drug at lower doses and more quickly than the approved medication. However, we caution that these are preclinical, animal studies and that clinical work may produce different results.

Hypertension

Hypertension grabbed the spotlight in early January with AstraZeneca's (NASDAQ: AZN) bid for the recently IPOed CinCor Pharma (NASDAQ: CINC). CinCor recently provided top-line data from its Phase II study that evaluated baxdrostat in hypertension patients. Baxdrostat is a selective aldosterone synthase inhibitor shown to lower aldosterone levels without affecting cortisol. The primary endpoint of the study was not met; however, there were large reductions in systolic blood pressure. AstraZeneca saw enough promise in the data to support further trials in hypertension and chronic kidney disease. Merger and acquisition activity in the space accentuates the unmet need for effective control of hypertension and provides a healthy backdrop for further work by Lexaria in this area.

Lexaria's latest update on its hypertension program was in late December 2022, where it provided more details on DHT-CBD absorption levels. The HYPER-H21-4 hypertension study using DHT-CBD was able to achieve a 46% greater human blood plasma level, or 33.3 mg/mL, than was achieved in a previous study using oral CBD solution for seizures related to Dravet syndrome. To compare the results of the HYPER-H21-4 study to the Dravet study, Lexaria provided a graph of the DHT-CBD results (with extrapolation) exhibiting the greater plasma CBD levels between the two approaches and included another data point from the Wheless *et al*. study (the triangle marker in the exhibit below).

Exhibit II – Comparison of Plasma Levels: DHT-CBD & Devinsky *et al.*[4,5,6]



[4] Devinsky, O., *et al.* Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. New England Journal of Medicine, May 2017.
[5] Wheless, J., *et al*. Pharmacokinetics and Tolerability of Multiple Doses of Pharmaceutical-Grade Synthetic Cannabidiol in Pediatric Patients with Treatment-Resistant Epilepsy. CNS Drugs, June 2019.
[6] Lexaria Press Release, December 21, 2022. Lexaria's DehydraTECH-CBD Achieves Superior Human Blood Absorption Levels.

The data support Lexaria's contention that DHT-CBD can be administered at lower doses than other CBD formulations and achieve therapeutic levels in the bloodstream. Benefits from the approach can reduce systemic levels of the drug, while achieving similar results using higher levels of CBD.

HYPER-H21-4 was structured as a randomized, double-blinded, placebo-controlled, cross-over study that dosed 66 male and female volunteers between the ages of 40-70. The study compared DehydraTECH cannabidiol (CBD) against a placebo. Enrollment criteria sought patients with elevated blood pressure, stage 1 hypertension or stage 2 hypertension.[7] Data were cataloged over the five weeks of dosing after recording baseline metrics. The first blood pressure measurement recorded to determine clinical endpoints was conducted over a 24-hour period at the end of the first 2.5 weeks and the second over a 24-hour period at the end of the second 2.5 weeks.

Previously reported results from the study showed an improvement in all time periods and for both systolic and diastolic pressures for subjects administered DehydraTECH CBD. Measurements of systolic and diastolic pressure for the first and second part of the dosing period compared to baseline ranged from 2.3 to 5.6 mm Hg.

Exhibit III – HYPER-H21-4 Results[8]

24-Hour BP Monitoring Change from Baseline	Dose Period 1 First 2.5 Weeks (mmHg)		Dose Period 2 Second 2.5 Weeks (mmHg)	
	DehydraTECH-CBD (225 mg - 300 mg daily)	Placebo	DehydraTECH-CBD (375 mg - 450 mg daily)	Placebo
MAP	-3.22 +/-0.90 *P* =0.002	+0.72 +/-0.78 *P* =1.000	-4.14 +/-0.69 *P* <0.001	-1.41 +/-0.91 *P* =0.387
SBP	-4.76 +/-1.24 *P* =0.001	+0.94 +/-0.99 *P* =0.993	-5.60 +/-0.81 *P* <0.001	+1.41 +/-1.16 *P* =0.688
DBP	-2.25 +/- 0.80 *P* =0.019	+0.67 +/-0.81 *P* =1.000	-3.25 +/-0.72 *P* <0.001	+1.30 +/-0.88 *P* =0.437

Safety was strong point for DehydraTECH CBD in the hypertension study with eight mild to moderate adverse events recorded in the active arm compared to six mild to moderate events in the placebo arm. No serious adverse events occurred. Liver enzymes were within normal ranges and there were no adverse hepatic changes reported.

Lexaria expects to have additional data releases including further examinations of performance of subpopulations within the evaluated group and qualitative assessments based on questionnaire responses. A peer reviewed article has been developed based on available data and will be in preparation to be published in a journal over the coming months. Next steps for the hypertension program are to conduct a Phase Ib study targeted to begin in 2023.

The data generated to date has demonstrated early safety and efficacy for DehydraTECH CBD and we anticipate that the upcoming Phase Ib study will continue the positive results as it has a similar design to HYPER-H21-4. Longer term goals for the program are to find a partner who will advance the work to a registrational study and send it on the FDA for approval. While this event is several years away, the data that has been released so far is supportive of further development.

Hypertension Study Details

Lexaria has launched four human hypertension studies that are evaluating 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 now reported topline results to investors as detailed in the previous section.

[7] Elevated blood pressure was defined as systolic and diastolic pressures of 120/80 to 139/80 mm Hg, stage 1 from 140/90 to 159/99 mm Hg and stage 2 of 160/100 to 179/109 mm Hg.
[8] Source: Lexaria Biosciences Press Release October 27, 2022.

Exhibit IV – Summary of DehydraTECH CBD Studies for Hypertension[9]

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

Hypertension Study HYPER-H21-3 Results
The third study evaluating DHT-CBT in hypertension began in November 2022. It was designed to measure acute pulmonary hypertension and cardiovascular effects under severe stress. Patients were exposed to lower levels of oxygen during their treatment to measure the effect on hypoxic pulmonary vasoconstriction. It was designed to evaluate the effect of DHT-CBD on pulmonary vascular function in normotensive individuals exposed to hypoxia. On April 14, 2022, Lexaria issued a press release announcing that the HYPER-H21-3 study had generated positive results with positive safety and efficacy findings.

Third study findings indicated a tendency (p=0.1) during 15 minutes of simulated low levels of oxygen (hypoxia) for reduced pulmonary artery systolic pressure (PASP) with DHT-CBD treatment versus placebo. Most notably, PASP was reduced by ~5 mmHg or 41% overall (p=0.045) in male participants specifically suggesting differences by sex in responsiveness to CBD treatment under hypoxic stress conditions. Males made up eight of the 16 subjects enrolled. Results for female participants was not provided.

Results from the study will be used to direct future research of DHT-CBD for management of pulmonary arterial pressure under hypoxic conditions (altitude exposure), related hypoxemic pathologies (severe lung disease) and pulmonary hypertension. The data will also support efforts to seek FDA approval via an investigational new drug (IND) application to begin formal, registered clinical testing in the treatment of hypertension.

Study design included eight female and eight male subjects aged from 18 to 35 years. Participants were given 30 minutes of rest following dosing where they inhaled normal 21% oxygen air followed by a 40-minute period of simulated hypoxia (12% oxygen) in order to simulate hypoxic pulmonary vasoconstriction and pulmonary hypertension. The results were intended to simulate conditions at high altitude or activities with diminished oxygen availability that could lead to hypoxic pulmonary vasoconstriction.

Hypertension Study HYPER-H21-4
Lexaria announced that the HYPER-H21-4 trial began enrolling in an April 19 press release. The 60-subject study, later increased to 66, was designed as a randomized, double blinded, placebo-controlled, cross-over study with elevated, mild or moderate hypertension. The primary endpoint is 24-hour ambulatory blood pressure. Secondary endpoints include vascular health including arterial stiffness and autonomic balance, electrocardiogram analysis, brain structure and function through MRI testing, blood biomarkers, renal and hepatic analysis, sleep quality, geriatric depression scale, perceived stress and Beck anxiety inventory.

Dosing began ahead of schedule and was announced as complete on July 27th. Maximum dose levels used in the study reached 5 mg/kg/day, which matches the lowest daily starting dose of CBD used in children for the approved treatment of Dravet syndrome.[10] No serious adverse events were reported during the study and DHT-CBD was well tolerated. Data from the study will be used to support an Investigational New Drug (IND) application with the FDA.

Patents

Lexaria was granted its first Canadian patent and 28th patent worldwide in late December 2022. The patent, entitled "Transdermal and/or dermal delivery of lipophilic active agents" relates to improved compositions and methods for transdermal and dermal delivery of cannabinoids, including cannabidiol (CBD) and tetrahydrocannabinol (THC). Similar patents in other jurisdictions remain pending. Skin-based delivery is an alternative to oral and inhalation routes and can provide advantages for localized treatment and reduce systemic exposure. Lexaria's 2018 study demonstrated improved CBD permeability using DehydraTECH compared with a control and the best performing commercial penetration enhancer.

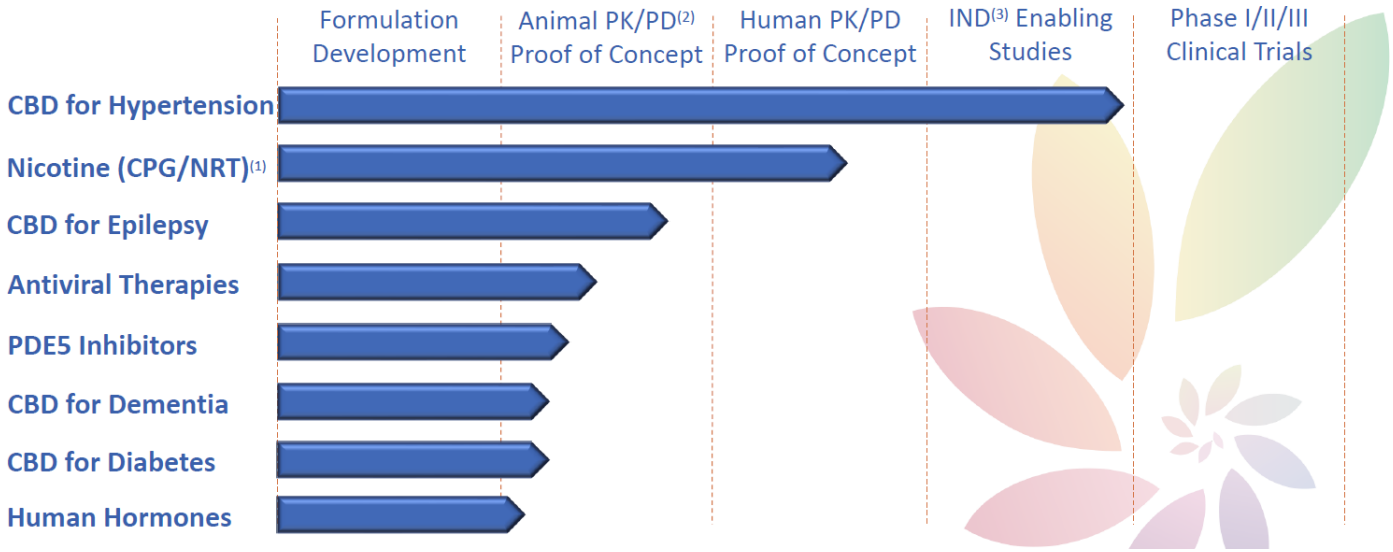
[9] Source: Company press releases and Zacks analyst compilation
[10] Dose is recommended to start at 2.5 mg/kg twice per day which is doubled after one week and increased to 20 mg/kg/day inappropriate circumstances. Source: Epidiolex FDA Label

Milestones

- Additional results from HYPER-H21-4 – 1Q:23
- Dosing completion in multiple studies – 1Q:23
  - Dementia (DEM-A22-1)
  - Diabetes (DIAB-A22-1)
  - Nicotine (NIC-H21-1)
- File investigational new drug application for hypertension Phase Ib – 1Q:23
- Readouts from ongoing studies - 2023
- DHT-CBD Phase Ib hypertension study – 2H:23

Pipeline

Exhibit V – DehydraTECH Pipeline[11]



Summary

Lexaria has wrapped up a busy 2022 with multiple new studies and results either underway or recently reporting data. The lead programs for the company in hypertension and nicotine have posted favorable results and support further clinical studies for the former and expanded relationships with partners for the latter. Lexaria's efficient use of capital has allowed the company's research and development activities to expand into new preclinical work including efforts in diabetes and dementia. While still early stage, these programs could be excellent partnership opportunities that will support further growth and potentially provide growth capital.

We expect additional data to come out for the hypertension and other active studies as well as a journal article that will provide additional clarity on study outcomes. Lexaria has outlined several milestones that it expects during the first quarter including dosing completion for multiple studies and the filing of an IND for DHT-CBD. IND clearance will support the start of a Phase Ib study in 2023 which will be the main value driver for the company's R&D platform. Further efforts include sharing the data with potential partners who will take the baton of the hypertension program for late-stage development and submission for approval with regulatory agencies. We maintain our $15 valuation.

[11] Source: Lexaria January 2023 Corporate Presentation.

PROJECTED FINANCIALS

Lexaria Bioscience Corp. - Income Statement

Lexaria Bioscience Corp.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues	**$723**	**$14**	**$31**	**$100**	**$195**	**$339**	**$1,275**	**$1,530**
YOY Growth	88%	-95%	-84%	-51%	529%	-53%	276%	
Gross Profit	$547	$8	$24	$81	$146	$260	$755	$918
Research & Development	$1,263	$459	$276	$752	$741	$2,227	$3,500	$3,605
General & Administrative	$4,971	$1,553	$1,197	$1,747	$710	$5,208	$3,725	$3,874
Other	($1,523)	$0	$0	$0	$0	$0	$0	$0
Income from operations	($4,164)	($2,003)	($1,449)	($2,418)	($1,305)	($7,175)	($6,470)	($6,561)
Operating Margin								
Discontinued operations	($22.0)	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($4,186)	($2,003)	($1,449)	($2,418)	($1,305)	($7,175)	($6,470)	($6,561)
Net Income	**($4,186)**	**($2,003)**	**($1,449)**	**($2,418)**	**($1,305)**	**($7,175)**	**($6,470)**	**($6,561)**
Net Margin	*-579%*	*-14434%*	*-4750%*	*-2425%*	*-669%*	*-2116%*	*-507%*	*-429%*
Reported EPS	**($0.95)**	**($0.35)**	**($0.25)**	**($0.41)**	**($0.21)**	**($1.21)**	**($1.04)**	**($0.87)**
Basic Shares Outstanding	4,391	5,727	5,911	5,951	6,090	5,920	6,200	7,500

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

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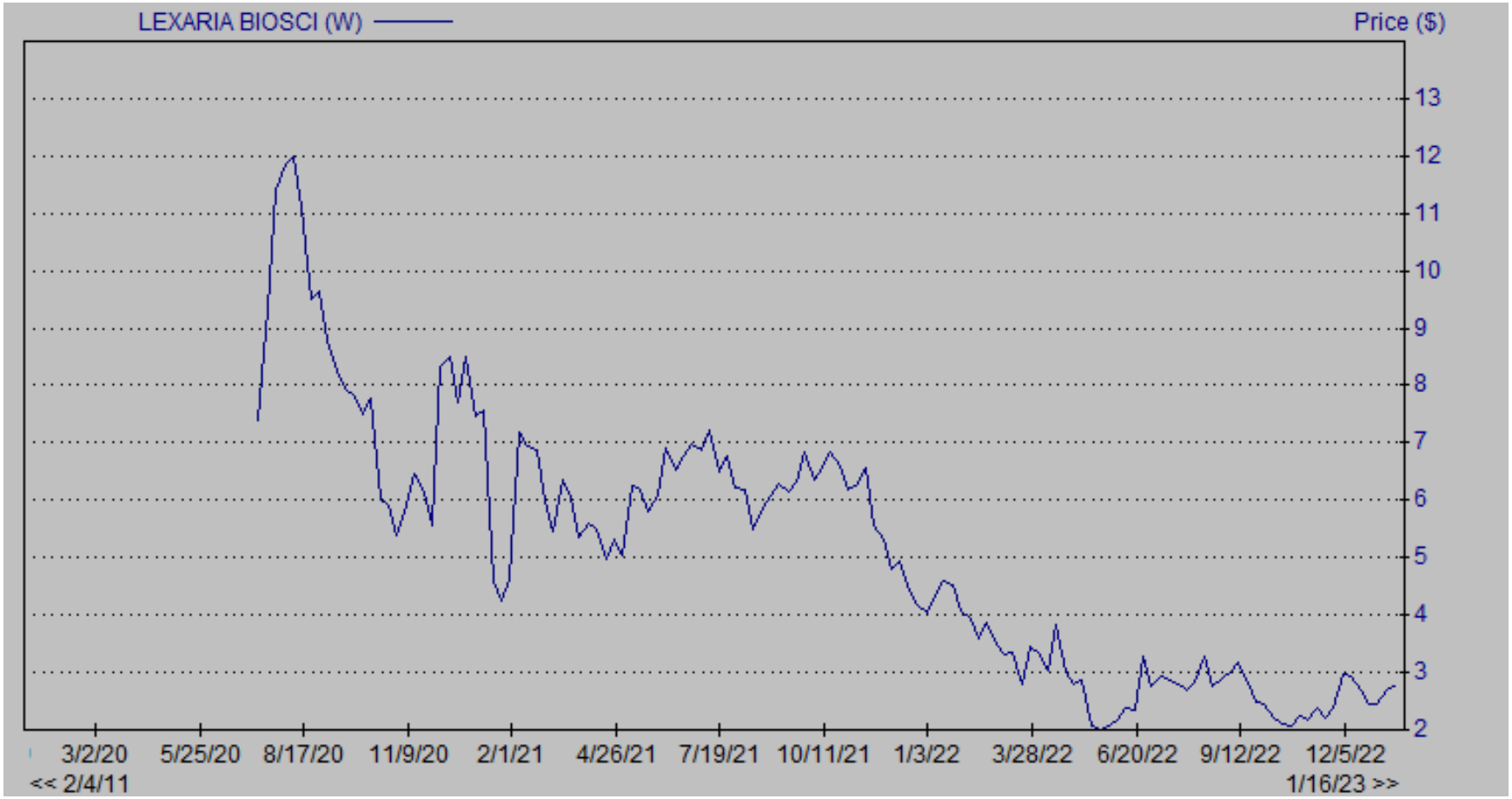
HISTORICAL STOCK PRICE

Lexaria Bioscience Corp. – Share Price Chart[12]



[12] Source: Zacks Research System

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