Zacks Small-Cap Research

Sponsored – Impartial – Comprehensive

October 31, 2022
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Lexaria Bioscience Corp. (LEXX: NASDAQ)

DehydraTECH CBD HYPER-H21-4 Results

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 (10/28/2022)	$2.23
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	**6.72**
52-Week Low	**1.80**
One-Year Return (%)	**-63.7**
Beta	**1.2**
Average Daily Volume (sh)	**38,731**
Shares Outstanding (mil)	**5.95**
Market Capitalization ($mil)	**13.3**
Short Interest Ratio (days)	**9.8**
Institutional Ownership (%)	**9.7**
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	$0.4 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	-$1.09 E
2023					-$1.04 E
2024					-$0.87 E

WHAT'S NEW

HYPER-H21-4 Results

In an October 27th press release, Lexaria Bioscience Corporation (NASDAQ: LEXX) reported impressive results from its human clinical hypertension study designated HYPER-H21-4. This is the fourth and most comprehensive of Lexaria's hypertension studies and 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.[1] 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.

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 I – HYPER-H21-4 Results[2]

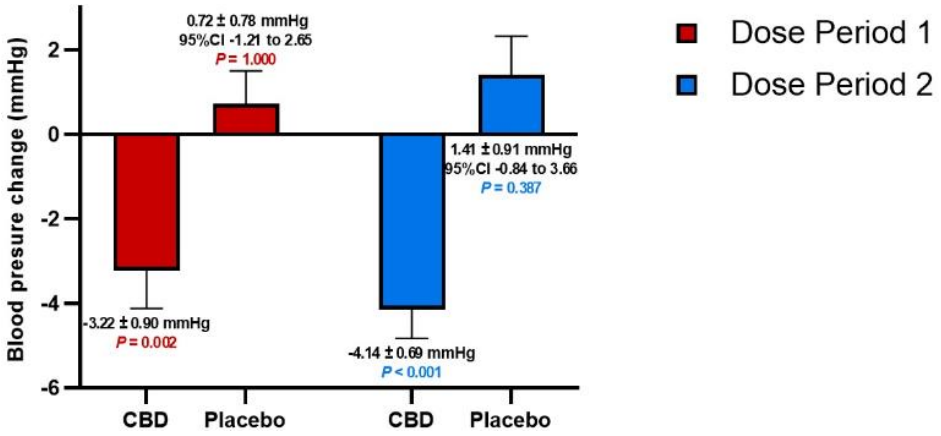
24-Hour BP Monitoring Change from Baseline	Dose Period 1 First 2.5 Weeks (mmHg)		Dose Period 2 Second 2.5 Weeks (mmHg)	
	DehydraTECH-CBD (225 mg - 300 mg daily)	Placebo	DehydraTECH-CBD (375 mg - 450 mg daily)	Placebo
MAP	-3.22 +/-0.90 *P* =0.002	+0.72 +/-0.78 *P* =1.000	-4.14 +/-0.69 *P* <0.001	-1.41 +/-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 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.

Additional graphical data was provided regarding the mean arterial pressure (MAP) compared to baseline. The data shows a statistically significant improvement compared with baseline and a 3.22 mm Hg lower reading for the DehydraTECH arm relative to baseline during the first half of the dosing period. In the second half of the dosing period, the difference was even greater where DehydraTECH also generated a statistically significant improvement relative to baseline of 4.14 mm Hg. The data is graphically represented in the following exhibit.

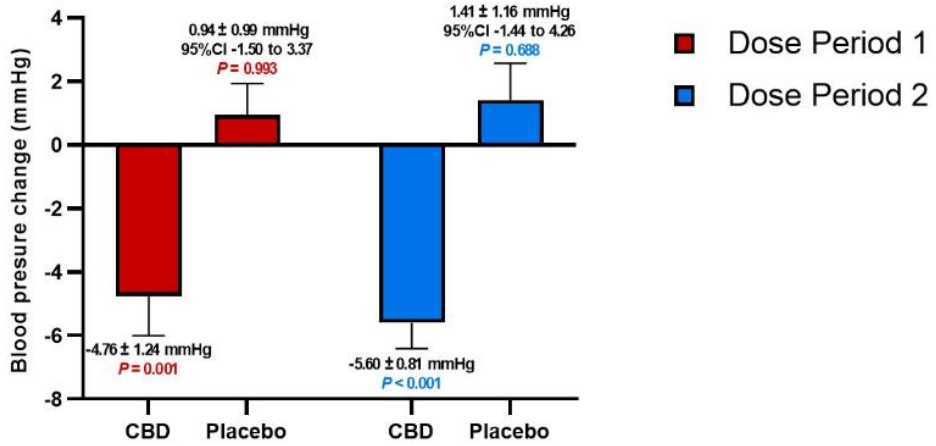
[1] Elevated blood pressure was defined as systolic and diastolic pressures of 120/80 to 139/80 mm Hg, stage 1 from 140/90 to 159/99 mm Hg and stage 2 of 160/100 to 179/109 mm Hg.
[2] Source: Lexaria Biosciences Press Release October 27, 2022.

Exhibit II – 24 Hour MAP Change from Baseline[3]



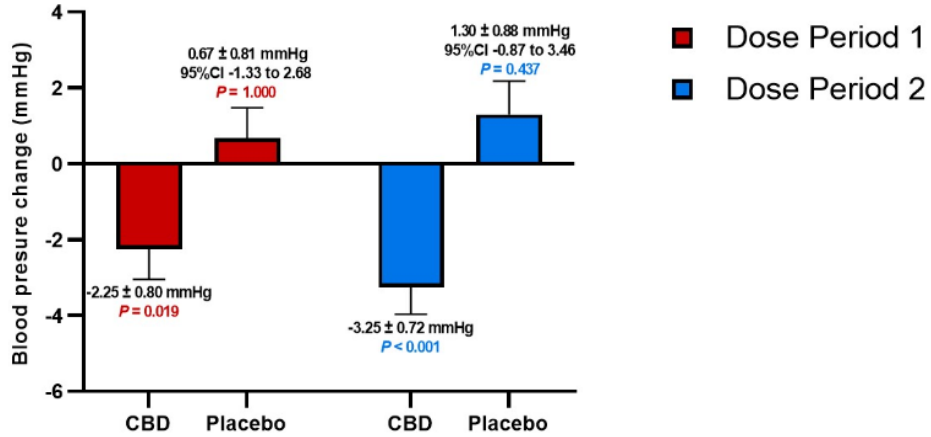
Systolic blood pressure (SBP) was reduced relative to baseline and placebo. Reductions were statistically significant across the board for each data segment and improvements relative to baseline were 4.76 and 5.60 mm Hg for the first and second halves of the dosing period respectively. Higher systolic blood pressure is the measure which has been most associated with a greater risk of stroke and heart disease.

Exhibit III – 24 Hour SBP Change from Baseline[4]



Lexaria also provided a graphic illustrating the comparative performance of patients' diastolic blood pressure (DBP). This metric was reduced for the DehydraTECH CBD arm by 2.25 and 3.25 mm Hg relative to baseline for the first 2.5 and second 2.5 week periods.

Exhibit IV – 24 Hour DBP Change from Baseline[5]



[3] Source: Lexaria Biosciences Press Release October 27, 2022.
[4] Source: Lexaria Biosciences Press Release October 27, 2022.
[5] Source: Lexaria Biosciences Press Release October 27, 2022.

Lexaria expects to have additional data releases in the coming months 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 which is 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 is several years away, the data that has been released so far is supportive of further development.

Lexaria Hypertension Studies

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 and examined diastolic pressure over a three-hour period and found that the pressure was lower in DHT-CBD subjects. 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.

Exhibit V – Summary of DehydraTECH CBD Studies for Hypertension[6]

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

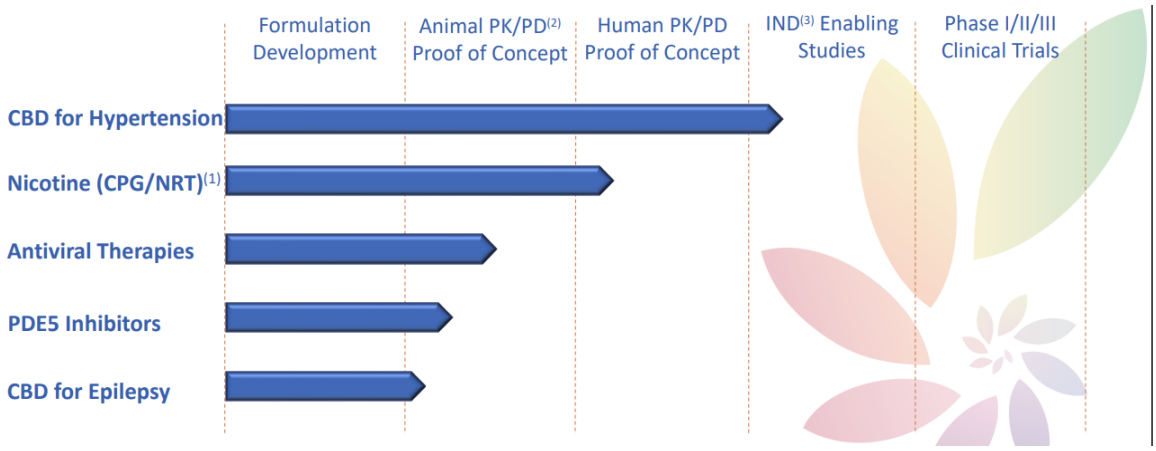
[6] Source: Company press releases and Zacks analyst compilation

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.[7] 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.

Pipeline

Exhibit VI – DehydraTECH Pipeline[8]



Summary

Lexaria has reported topline results from its most important clinical work conducted to date: the DehydraTECH CBD trial designated HYPER-H21-4. The results were favorable with statistically significant reductions in MAP, SPB and DBP for both the first half and second half of the measurement period. Reductions versus baseline ranged from 2.3 to 5.6 mm Hg and were accompanied by a favorable safety profile. We expect additional data and a journal article to come out over the next months that will provide additional clarity on study outcomes. Next steps for the hypertension program are to submit and receive clearance for an IND application. IND clearance will support the start of a Phase Ib study in 2023. 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.

[7] 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
[8] Source: Lexaria October 2022 Corporate Presentation.

PROJECTED FINANCIALS

Lexaria Bioscience Corp. - Income Statement[9]

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

.

HISTORICAL STOCK PRICE

Lexaria Bioscience Corp. – Share Price Chart[10]

[10] Source: Zacks Research System

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. This research report was prepared under the aforementioned engagement.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover.
SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN DISCLAIMER

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada and is not an associated person of any Canadian registered adviser and/or dealer and, therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.