

## Lexaria Bioscience Corp.

(LEXX: NASDAQ)

### Put Your Drinks Up! Four Deals Signed in June

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 (8/2/2022)

\$2.78

Valuation

\$15.00

## SUMMARY DATA

52-Week High	7.20
52-Week Low	1.85
One-Year Return (%)	-56.6
Beta	1.4
Average Daily Volume (sh)	61,985

Shares Outstanding (mil)	5.95
Market Capitalization (\$mil)	16.5
Short Interest Ratio (days)	4.0
Institutional Ownership (%)	8.0
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
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## 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.

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

## ZACKS ESTIMATES

### Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Nov)	(Feb)	(May)	(Aug)	(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	Q2	Q3	Q4	Year
	(Nov)	(Feb)	(May)	(Aug)	(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

Lexaria Bioscience Corporation (NASDAQ: LEXX) experienced a substantial amount of activity on both the drug development front and in closing agreements with partners since the end of the fiscal second quarter. The company announced four material partnerships in June that will provide a variety of upfront, milestone and royalty opportunities over the next quarters and years to come. It has also updated investors on other events including the results of its annual meeting, the grant of patents and the filing of a pre-investigational new drug (IND) meeting request with the FDA. See below for a summary of third quarter financial performance, Lexaria's new relationships and additional detail on the company's operations.

### 3Q:22 Results

Lexaria filed its third quarter fiscal year 2022 [Form 10-Q](#) on July 14, 2022. The company reported 3Q:22 revenues of \$100,000, and total operating expense of \$2.6 million resulting in net loss of (\$2.4) million or (\$0.41) per basic and diluted common share.

For the third quarter ending May 31, 2022 and versus the same ending May 31, 2021:

- Revenue totaled \$100,000, down 51% from \$204,000 with product revenues of \$94,100 down 27% and other revenues of \$5,600 rising 23%. Licensing revenues were \$0 in contrast to the prior year's \$70,600. Lexaria's primary customer in the B2B product revenue stream has been delayed in chain-store rollouts causing them to work down overstocked inventory and delay new purchases;
- Research and development expenses totaled \$752,000, increasing 65% from \$454,000 as Lexaria undertook several studies within its 2022 applied research and development program focusing on DHT-CBD to treat hypertension and costs related to preparation of the investigative new drug (IND) filing;
- General and administrative expenses totaled \$1.7 million, down 20% from \$2.2 million due primarily to lower consulting and professional fees partially offset by increased spending on investor relations and advertising;
- Net loss was (\$2.4) million, or (\$0.41) per share, compared to net loss of (\$2.6) million or (\$0.50) per share.

As of May 31, 2022, cash and marketable securities totaled \$7.1 million - a sequential \$1.9 million decline. Cash burn for the first nine months of FY:22 was approximately (\$3.8) million. Lexaria carries \$8,000 in loan payable on its balance sheet.

### Recent Deals

Lexaria signed four deals in June that expand the use of DehydraTECH in several product areas and geographies. The most impactful of these arrangements is with Premier Wellness Science, which will soon start paying license fees and launch products using the DehydraTECH technology in Japan. Relationships with AnodGen and Valcon are longer term in nature as these partners seek to become pharmaceutical-grade manufacturers of cannabinoid products. BevNology takes over from Lexaria's former Salt Lake, Utah facility to provide contract manufacturing services, beverage capacity and act as a science center for these operations.

In addition to the new deals, long-time partner [Cannadips](#) is expanding internationally with its CBD pouches into Europe, Japan, and South Africa. The product is offered in 6,500 stores in the US.

### BevNology

Lexaria's most recent arrangement which occurred in late June, [licensed](#) the use of DehydraTECH to [BevNology](#), an Atlanta-based purveyor of food and beverages. Two agreements were signed. The first is a manufacturing operating agreement that will allow third parties to use DehydraTECH modified ingredients for consumer goods. BevNology will act on behalf of partner brands that wish to use DehydraTECH and need a third-party manufacturer. The second agreement is a commercial license that allows BevNology to offer DehydraTECH products with cannabinoid products. The arrangement is non-exclusive for powdered product but is exclusive in the United States for liquid formulations. Minimum fee payments are required to maintain the license and royalties will be owed on product sales including the technology.

## AnodGen Bioceuticals

As reported in a June 8<sup>th</sup> [press release](#), Lexaria granted a pharmaceutical license for use of its DehydraTECH platform by [AnodGen Bioceuticals](#) for manufacturing and distributing cannabidiol (CBD) active pharmaceutical ingredient (API) powders in Europe, Australia and New Zealand. The license includes pharmaceutical and medical product applications for psychoactive cannabinoids and medical product applications for non-psychoactive cannabinoids and can be extended to third party companies to use in their own products. Products qualifying under the license will be designated by a national regulator as a medical product, drug, nutraceutical, pharmaceutical or biopharmaceutical under its cannabinoid product license rights. Lexaria will receive royalties for AnodGen products sold using DehydraTECH. Although rates have not been disclosed, royalties received for pharmaceutical products are generally greater than those received for consumer products.

Anodgen is a contract manufacturing organization (CMO) that will manufacture and distribute active pharmaceutical ingredients for the pharmaceutical industry by focusing on plant-based medicine. Anodgen specializes in sourcing and compounding custom CBD APIs and other customized blends. It has recently signed two research memorandums of understanding (MOUs) with multiple U.S. universities for research collaboration.

## Premier Wellness Science

Lexaria granted an exclusive license to [Premier Wellness Science Co.](#) for use of the DehydraTECH technology in a variety of CBD products as detailed in a June 3<sup>rd</sup> [news release](#). The products may be in oral liquid or non-liquid form and may be used in the topical, hair-care, lip-care and cosmetics segments. The arrangement includes minimum payments of \$4.5 million to be paid over the first five years of the deal to maintain exclusivity. The license payments will start from a small base and grow as the arrangement moves into its final years. First payments will be made to Lexaria on September 1<sup>st</sup>. Royalty percentages were not disclosed nor were Premier sales forecasts; however, the press release noted that under the worst-case sales projection by Premier, Lexaria could receive annual royalties of over \$5 million.

Technology transfer between the companies began prior to the initial public announcement providing a head start to an expected [launch](#) of DehydraTECH-powered CBD products under the KO brand in 2Q:23. Premier will create an e-commerce infrastructure and digital marketing campaign to support the brand.

Premier is a wholesale and retail marketer of cosmetics and health foods in Japan which are offered under the DUO and CANADEL brands. The company is also involved provides information and consulting services to entities involved in the anti-aging, beauty and health industry. It also offers market research and data collection and analysis for its clients. Premier is a subsidiary of Premier Anti-Aging Co which trades on the Tokyo Stock Exchange under code 4934.

## Valcon Medical

Lexaria and [Valcon Medical A/S](#) signed an agreement granting the latter rights to use the DehydraTECH platform for medical cannabis applications as [described](#) in a June 2<sup>nd</sup>, 2022 press release. The products subject to the license are classified as non-registered medical products and authorized through country-level programs or EU Commission registered cannabis products. Examples of intended products include bulk powders, solid oral dosage forms, powder-filled capsules, compressed tablets, pills, oral melts and topical creams and lotions with or without patch integration. It is a non-exclusive license with milestone fees due Lexaria upon completion of batch validation and marketing authorization application approvals. Royalties on sales will also be due from related products sold by Valcon using the DehydraTECH technology. While financial details of the arrangement were not made public, in the pharmaceuticals space, royalties are normally in the 6-10% range.

Valcon Medical is a European contract manufacturing organization (CMO) that is good manufacturing practice (GMP) certified and licensed in Denmark to manufacture medical cannabis. The CMO works with partners to provide contract processing and bulk extract services. It can also produce white label product for other companies to commercialize.

## Ongoing Drug Studies

### *Hypertension*

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 con-

firmed that DHT can reduce arterial stiffness. The fourth study began in early April 2022 and has enrolled 64 volunteers, completed dosing and reports no serious adverse events.

#### Exhibit I – Summary of DehydraTECH CBD Studies for Hypertension<sup>1</sup>

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	2H:22	64 subject RCT w/ placebo control	Europe	3/150 mg/day

#### *Hypertension Study HYPER-H21-3 Results*

The third study evaluating DHT-CBD 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 64, is of a randomized, double blinded, placebo-controlled, cross-over design 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 27<sup>th</sup>. No serious adverse events were reported as a result of the dosing. 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.<sup>2</sup> No serious adverse events have been reported and DHT-CBD has been well tolerated. Data from the study will be used to support an Investigational New Drug (IND) application with the FDA. Results from the trial will also aid in the design of the registered trial.

#### *Nicotine Program Updates*

Over the last couple months, Lexaria has enjoyed several items of good news for its nicotine program. As we mentioned in our initiation, Lexaria has worked with Altria to develop new methods of nicotine delivery and received \$1 million in upfront payments to support development efforts. While the elements of this agreement have largely ex-

<sup>1</sup> Source: Company press releases and Zacks analyst compilation

<sup>2</sup> 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 in appropriate circumstances. Source: [Epidiolex FDA Label](#)

pired, Lexaria has forged ahead in the nicotine space encouraging Altria to come back for another round. While details were sparse, on April 11, Lexaria [announced](#) a new agreements with Altria Client Services, LLC where it will provide DHT powder-based nicotine formulations to Altria. Lexaria will receive a fee for the formulations, which will be evaluated by Altria. The arrangement will be in effect for one year.

Last October, Lexaria shared results from its NIC-A21-1 study finding that DHT nicotine was able to achieve a higher peak and sustained levels of nicotine in blood compared with the control pouch in an animal study which we discuss in a [previous report](#). Since then other studies have been [advanced](#) NIC-H22-1 which is expected to begin dosing in a few weeks. The 36-subject human study is a pharmacokinetic, randomized, double blinded, cross-over study intended to compare Lexaria's DHT-nicotine pouch performance to competing brands currently sold in the US such as ON! and Zyn. Data collection will include time to maximum concentration ( $T_{MAX}$ ), the peak concentration of nicotine ( $C_{MAX}$ ) and total nicotine in blood serum as represented by the area under the curve (AUC). The study will also examine throat burn, user experience and other secondary endpoints. Dosing is expected to begin this summer.

Lexaria has also made progress in intellectual property protection for its nicotine programs and was recently [awarded](#) an oral nicotine patent in Australia. The protected claim is entitled "Compositions Infused with Nicotine Compounds and Methods of Use Thereof." Protection is extended to most oral forms of nicotine including pills, tablets, lozenges, capsules, pouches, gums and sprays. It also covers multiple forms of nicotine including free base nicotine, nicotine salts, polymer resins of nicotine and other forms of nicotine complexes. The patent is expected to expire in April 2039. A patent was also [granted](#) in Japan entitled "Lipophilic Active Agent Infused Compositions With Reduced Food Effect" which recognizes DehydraTECH's ability to deliver active pharmaceutical ingredients more efficiently regardless of the presence of foods within the gastrointestinal system.

### *Epilepsy*

One of Lexaria's closest comparisons for DHT-CBD is Jazz Pharmaceutical's (NASDAQ: JAZZ) Epidiolex, a CBD product which was approved in August 2021 for a certain type of epilepsy. We think that Jazz would make a good partner for Lexaria for a collaboration in advancing CBD-based treatments such as Lexaria's active hypertension program. Perhaps in an attempt to attract Jazz' attention, Lexaria has announced that it will begin a DHT-CBD epilepsy program that will compare efficacy with Jazz' Epidiolex for reducing seizure activity. The program is designated EPIL-A21-1 and will use a third-party laboratory to evaluate rodents in an acute seizure model and a chronic chemically induced seizure model. The design of the animal study mirrors that used to advance Epidiolex pre clinically. The study will be funded internally.

### **CEO Interview**

We recently spoke with CEO Chris Bunka about the DehydraTECH platform, Lexaria's hypertension and nicotine programs and the company's competitive advantage with respect to input cost, which is particularly relevant in today's environment. See below for links to the five videos in the series.

**Exhibit II – Lexaria CEO Chris Bunka<sup>3</sup>**

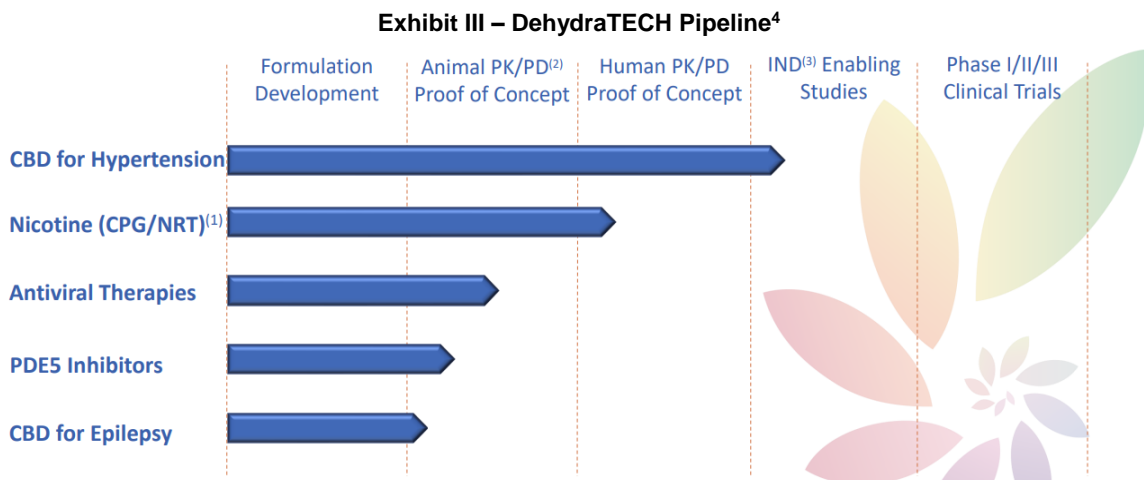


<sup>3</sup> Source: Lexaria Biosciences CEO Chris Bunka YouTube video screen capture, June 2022.



- I. [Introduction](#)
- II. [What is DehydraTECH?](#)
- III. [Lexaria's Work in Hypertension](#)
- IV. [Lexaria's Nicotine Efforts](#)
- V. [Fireside Chat](#)

## Pipeline



## Milestones (Calendar Quarters Used)

- Study [examining](#) cannabinoids and SARS-CoV-2 - January 2022
- Publication of [results](#) for PDE5-A21-1 animal study – February 2022
- Animal study (EPIL-A21-1) for pediatric seizures using CBD – March 2022
- Hypertension study (HYPER-H21-4) dosing – April 2022
- New Altria nicotine [agreement](#) – April 2022
- [Patent granted](#) for delivery of antiviral drugs – April 2022
- Hypertension study (HYPER-H21-3) [readout](#) – April 2022
- Human sublingual (buccal) tissue study in nicotine – Spring 2022
- License granted to CMO Valcon Medical – June 2022
- License granted to Premier Wellness Science – June 2022
- License granted to AnodGen Bioceuticals – June 2022
- Manufacturing & Licensing agreement with BevNology – June 2022
- Nicotine compositions patent granted in Australia – June 2022
- DehydraTECH patent [granted](#) in Japan – July 2022
- Briefing book submitted to FDA for pre-IND meeting on hypertension program – July 2022
- Completion of dosing for HYPER-H21-4 – July 2022
- Completion of dosing for EPIL-A21-1 – Summer 2022
- Hypertension study (HYPER-H21-4) results – 3Q:22
- Commercial client partners introducing DHT skin products – 3Q:22
- Human nicotine study NIC-H22-1 launch – 2H:22
- Pre-IND [meeting](#) with the FDA for CBD in hypertension – July 2022
- IND submission to FDA for CBD in hypertension – late 2022/early 2023
- Material agreement with industry partner in nicotine, pharma or other – 2022/2023

<sup>4</sup> Source: Lexaria July 2022 Corporate Presentation.

## **Annual Meeting**

Lexaria held its 2022 annual meeting on May 31, 2022 where votes on directors and auditors were submitted. All nominated directors and auditor Davidson & Company LLP were approved. Approximately half of all shareholders were represented in person or by proxy at the meeting. Additional matters that received a favorable vote include approval of compensation granted to executive officers, and approval of the acts of the directors since the prior shareholder meeting, which encompasses any transactions effected, contracts signed or other lawful acts on behalf of the company.

## **Summary**

Lexaria signed four deals in June that can expand the product set and geographies where DehydraTECH is used. The most important of these arrangements, Premier, will generate cash flows beginning in September and has the potential for material contributions in coming years. Other arrangements are in earlier stages of development but set the stage for license fees and the expansion of use of DehydraTECH. Work with BevNology will provide a contract manufacturer and a development partner for Lexaria that expands DehydraTECH's utility and products set. We also expect to see geographical expansion from existing partner Cannadips, which is branching out into three new continents. Work in hypertension has continued with the fourth study completing dosing and IND submission near at hand. The nicotine program recently generated favorable performance from the NIC-A21-1 study and will soon begin the NIC-H22-1 study comparing absorption of DehydraTECH product with other nicotine pouches. Looking ahead, the company anticipates signing a material deal in the next several quarters which could provide upfront payments in excess of annual cash burn, materially extending the runway for the company's research operations. We maintain our \$15 valuation.

## PROJECTED FINANCIALS

### Lexaria Bioscience Corp. - Income Statement<sup>5</sup>

Lexaria Bioscience Corp.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
<b>Total Revenues</b>	<b>\$723</b>	<b>\$14</b>	<b>\$31</b>	<b>\$100</b>	<b>\$195</b>	<b>\$339</b>	<b>\$1,275</b>	<b>\$1,530</b>
YOY Growth	88%	-95%	-84%	-51%	529%	-53%	276%	
<b>Gross Profit</b>	<b>\$547</b>	<b>\$8</b>	<b>\$24</b>	<b>\$81</b>	<b>\$146</b>	<b>\$260</b>	<b>\$755</b>	<b>\$918</b>
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
<b>Income from operations</b>	<b>(\$4,164)</b>	<b>(\$2,003)</b>	<b>(\$1,449)</b>	<b>(\$2,418)</b>	<b>(\$1,305)</b>	<b>(\$7,175)</b>	<b>(\$6,470)</b>	<b>(\$6,561)</b>
<i>Operating Margin</i>								
Discontinued operations	(\$22.0)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Pre-Tax Income</b>	<b>(\$4,186)</b>	<b>(\$2,003)</b>	<b>(\$1,449)</b>	<b>(\$2,418)</b>	<b>(\$1,305)</b>	<b>(\$7,175)</b>	<b>(\$6,470)</b>	<b>(\$6,561)</b>
<b>Net Income</b>	<b>(\$4,186)</b>	<b>(\$2,003)</b>	<b>(\$1,449)</b>	<b>(\$2,418)</b>	<b>(\$1,305)</b>	<b>(\$7,175)</b>	<b>(\$6,470)</b>	<b>(\$6,561)</b>
<i>Net Margin</i>	-579%	-14434%	-4750%	-2425%	-669%	-2116%	-507%	-429%
<b>Reported EPS</b>	<b>(\$0.95)</b>	<b>(\$0.35)</b>	<b>(\$0.25)</b>	<b>(\$0.41)</b>	<b>(\$0.21)</b>	<b>(\$1.21)</b>	<b>(\$1.04)</b>	<b>(\$0.87)</b>
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

<sup>5</sup> Financial statement information presents data as originally reported.



## HISTORICAL STOCK PRICE

Lexaria Bioscience Corp. – Share Price Chart<sup>6</sup>



<sup>6</sup> Source: Zacks Research System

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