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Lexaria Discusses Valuation Metrics for Biotech Industry

Third Party Analysis for Biotech and Pharma Industries

KELOWNA, BC / ACCESSWIRE / August 11, 2022 /Lexaria Bioscience Corp. (Nasdaq:LEXX) (Nasdaq:LEXXW) (the "Company" or "Lexaria"), a global innovator in drug delivery platforms is providing the following information to its stakeholders as an aid to conveniently researching and understanding various non-affiliated third-party sources and their methodologies for valuing biotech and pharmaceutical companies.

["Biotech companies with little to no revenue can still be worth billions"](#) says Raphael Rottgen, CFA, FRM. While valuations can be extremely low or extremely high, there is often underlying logic in identifying risks and arriving at those valuations. Developing new drugs can have significant costs of over \$1 billion and can take as long as 10 to 15 years to reach the market.

According to the U.S. Food and Drug Administration ("FDA"),[there are five steps to the drug development process](#):

- Step 1: Discovery and Development
- Step 2: Preclinical Research
- Step 3: Clinical Research
- Step 4: FDA Drug Review
- Step 5: FDA Post-Market Drug Safety Monitoring

Lexaria's DehydraTECH-CBD for hypertension program is currently operating within Step 3 using the FDA descriptions - various human studies seeking to evidence both tolerability/safety as well as efficacy for intended purposes. Interestingly, of the [5,000 - 10,000 compounds examined](#) and tested in the Discovery step above, not more than about 250 successfully complete the Preclinical Research step; DehydraTECH-CBD has already reached and surpassed this Preclinical Research stage.

Many investors and analysts use a [discounted cash flow](#) ("DCF") model as one method of trying to understand the [present value](#) ("PV") of a company. Understanding a defined sector's patient size, value of products, comprehensive opportunities, risks, and development timelines are just some of the many datapoints that contribute towards understanding potential valuations for that biotech or early-stage pharmaceutical company. Some have found [this article sourced from Investopedia](#) to be useful to contemplate biotech valuation potential.

In [a study conducted by McKinsey](#) that evaluated the 20 years from 1996 until 2016, total returns to shareholders from the biotech sector were 12% per annum, while the S&P 500 delivered 8% per annum during the same period. The Nasdaq biotech index is represented by the ETF; IBB. From the 2008 market lows, that index climbed nearly 1,000% to the all-time highs reached in August, 2021. It then declined by 41% to the recent low reached in June, 2022.

Bay Bridge Bio has made available [an extensive valuation guide](#) and set of online tools to help people understand potential valuation outcomes for different biotech companies or projects. Focusing on the above-referenced FDA drug development Steps 2 and 3 (Pre-Clinical and Clinical Research), Bay Bridge Bio looks in more detail at the widely utilized "Phase I, Phase II and Phase III" clinical trials often cited by the biotech industry within Step 3. Their valuation expectations PER DRUG MOLECULE are presented in the table below.

	Start of Phase I	Start of Phase II	Start of Phase III
Valuation	\$88,000,000	\$248,000,000	\$1,119,000,000
Probability of FDA Approval	12%	20%	56%

More sophisticated investors know that there are still finer-grained thresholds and opportunities within the FDA drug evaluation and registration process. Lexaria has commented many times that DehydraTECH processing of a molecule does NOT appear to create a new chemical entity ("NCE") or new molecular entity ("NME"). According to [this article published at Pharma Tech Outlook](#), that distinction is important as it is favorable for Lexaria to pursue an abbreviated/accelerated drug evaluation and [registration pathway known as 505\(b\)\(2\)](#) where Lexaria would rely in part on already known data from previously FDA-approved CBD product(s). "The advantages of 505(b)(2) are significant...and... the clinical program is typically much less comprehensive due to the 505(b)(2) applicant's ability to reference the innovator's approved product."

Of note, Lexaria was pleased to report in its announcement of August 10, 2022, that the FDA deemed Lexaria's plans to pursue the 505(b)(2) regulatory pathway for DehydraTECH-CBD as appropriate, by way of its recent pre-Investigational New Drug ("pre-IND") meeting outcome. Analysis has shown that 505(b)(2) applications have [roughly twice the FDA-approval rate](#) of NME applications.

Valuation of equities is a complex task with innumerable risks and rewards that include far-reaching macro events as well as company-specific developments. It is nearly impossible to foresee all risks and rewards, but underlying logic-based evaluation is one way to provide a realistic framework of expectations that investors can use in their analysis.

About Lexaria Bioscience Corp.

Lexaria Bioscience Corp.'s patented drug delivery technology, DehydraTECH™, improves

the way active pharmaceutical ingredients (APIs) enter the bloodstream by promoting more effective oral delivery. Since 2016, DehydraTECH has repeatedly demonstrated the ability to increase bio-absorption with cannabinoids, antiviral drugs, PDE5 inhibitors and more. DehydraTECH has also evidenced an ability to deliver some drugs more effectively across the blood brain barrier. Lexaria operates a licensed in-house research laboratory and holds a robust intellectual property portfolio with 26 patents granted and roughly 50 patents pending worldwide. For more information, please visit www.lexariabioscience.com.

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This press release includes forward-looking statements. Statements as such term is defined under applicable securities laws. These statements may be identified by words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions. Such forward-looking statements in this press release include, but are not limited to, statements by the company relating the Company's ability to carry out research initiatives, receive regulatory approvals or grants or experience positive effects or results from any research or study. Such forward-looking statements are estimates reflecting the Company's best judgment based upon current information and involve a number of risks and uncertainties, and there can be no assurance that the Company will actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements. As such, you should not place undue reliance on these forward-looking statements. Factors which could cause actual results to differ materially from those estimated by the Company include, but are not limited to, government regulation and regulatory approvals, managing and maintaining growth, the effect of adverse publicity, litigation, competition, scientific discovery, the patent application and approval process, potential adverse effects arising from the testing or use of products utilizing the DehydraTECH technology, the Company's ability to maintain existing collaborations and realize the benefits thereof, delays or cancellations of planned R&D that could occur related to pandemics or for other reasons, and other factors which may be identified from time to time in the Company's public announcements and periodic filings with the US Securities and Exchange Commission on EDGAR. The Company provides links to third-party websites only as a courtesy to readers and disclaims any responsibility for the thoroughness, accuracy or timeliness of information at third-party websites. There is no assurance that any of Lexaria's postulated uses, benefits, or advantages for the patented and patent-pending technology will in fact be realized in any manner or in any part. No statement herein has been evaluated by the Food and Drug Administration (FDA). Lexaria-associated products are not intended to diagnose, treat, cure or prevent any disease. Any forward-looking statements contained in this release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements or links to third-party websites contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

INVESTOR CONTACT:

George Jurcic - Head of Investor Relations

ir@lexariabioscience.com

Phone: 250-765-6424, ext 202

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