

This management's discussion and analysis ("**MD&A**") of LexaGene Holdings Inc. ("LexaGene" or the "Company") contains "forward-looking information" within the meaning of Canadian securities legislation ("forward-looking statements"). These forward-looking statements are made as of the date of this MD&A and the Company does not intend, and does not assume any obligation, to update these forward-looking statements, except as required under applicable securities legislation. Forward-looking statements relate to future events or future performance and reflect management's expectations or beliefs regarding future events. In certain cases, forward-looking statements can be identified by the use of words such as "plans", "expects" or "does not expect", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "objective", "predict", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases or statements that certain actions, events or results "may", "will", "could", "would", "should", "might" or "will be taken", "occur" or "be achieved" or the negative of these terms or comparable terminology. In this document, certain forward-looking statements are identified by words including "may", "future", "expected", "intends" and "estimates". By their very nature forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The Company provides no assurance that forward-looking statements may prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements.

The Company's anticipated future operations are forward-looking in nature and, as a result, are subject to certain risks and uncertainties. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, undue reliance should not be placed on them as actual results may differ materially from the forward-looking statements. 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 other factors may not affect the accuracy of such forward-looking statements. Such factors include but are not limited to the following:

- changes in general economic, market and business conditions and product demand;
- changing exchange rates;
- changes in the competitive environment in the markets in which LexaGene operates;
- changes in laws, regulations and decisions by regulators that affect LexaGene or the markets in which it operates;
- opportunities that may be presented to and pursued by LexaGene;
- LexaGene's ability to meet its working capital needs at the current level in the short term; and
- expectations with respect to raising capital.

This MD&A was prepared by management as of October 26, 2021 and is supplemental to and should be read in conjunction with the Company's unaudited condensed consolidated interim financial statements for the six months ended August 31, 2021 and the audited consolidated financial statements for the year ended February 28, 2021 and the accompanying notes thereto (collectively, "Financial Statements"). The information contained in this MD&A is presented as of the date of the Financial Statements and is current to that date unless otherwise stated. The results reported herein have been derived from consolidated financial statements prepared in accordance with the International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board.

All amounts are expressed in United States dollars unless otherwise noted.

This MD&A is intended to assist the reader in better understanding operations and key financial results as of the date of this report. The information contained in this MD&A have been reviewed and approved by the Company's Board of Directors on October 26, 2021.

Additional information relating to the Company is available on the Company's website at [www.lexagene.com](http://www.lexagene.com) and on SEDAR at [www.sedar.com](http://www.sedar.com).

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## OUR BUSINESS

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LexaGene is a molecular diagnostics company that develops diagnostic systems for pathogen detection and genetic testing for other molecular markers for on-site rapid testing in veterinary diagnostics, and for use in open-access markets such as food and water safety, clinical research, agricultural testing and biodefense. The MiQLab™ system delivers excellent sensitivity, specificity, and breadth of detection and can return results in approximately two hours. The unique open-access feature is designed for custom testing so that end-users can load their own real-time PCR assays onto the instrument to target any genetic target of interest.

The Company's shares trade on the TSX Venture Exchange (the "Exchange") under the symbol LXG and on the OTCQB Venture Market in the United States under the symbol LXXGF.

### COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the recent outbreak of a novel and highly contagious form of coronavirus, known as COVID-19, to be a pandemic. Since then, LexaGene's development and material procurement and sales processes have been impacted with long lead-time delays and restricted travel. LexaGene was able to retain all of its key employees and received a loan in May 2020, under the Paycheck Protection Program of the Coronavirus Aid, and Economic Security (CARES) Act for \$108,178 (the "PPP Loan").

The Company cannot accurately predict the on-going impacts COVID-19 will have on its operations and the ability of others to meet their obligations with the Company. Unchanged from the last reporting period, LexaGene is continually monitoring the situation closely and may take additional measures to reduce its costs and preserve its liquidities.

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## OPERATIONAL HIGHLIGHTS, EVENTS AND FUTURE PLANS

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LexaGene was founded by its Chief Executive Officer Dr. John (Jack) Regan in October of 2016. Dr. Regan leveraged his vast experience in infectious disease and bio-threat detection and invented the technology that is being commercialized at LexaGene.

As of October 26, 2021, LexaGene has 43 employees in the United States.

### Description of Products

LexaGene's MiQLab System is capable of processing a sample and returning results in approximately 2 hrs, depending on the size of the sample being processed and whether the screening is for RNA or DNA pathogens. The instrument automates the six steps that would normally be performed by a skilled molecular biologist. Namely, the instrument 1) breaks down cell walls to expose genetic material, 2) purifies the genetic material away from the cell walls and other matter in the sample, 3) assembles a series of reactions that are specific for the targeted genetic sequences, 4) amplifies the genetic material using the polymerase chain reaction (PCR), 5) optically monitors these reaction mixtures for the presence of amplified PCR products, and 6) generates a report that identifies the genetic targets found in each sample. For each processed sample, the instrument is capable of screening for 10 pathogens and 33 genes and variants in a single-use disposable cartridge of its second-generation panel.

The MiQLab System has two unique features that are currently not available in any other commercial product for automated bio-detection. These features make the MiQLab a first of its kind system.

The first unique feature is the 'open-access' nature of the MiQLab. Open-access allows users the flexibility to customize the tests the instrument runs, so they can target any genetic sequence of interest. In contrast, LexaGene's competitors only manufacture cartridges that already contain reagents for specific genetic targets. This prevents customers that are interested in detecting other sequences (e.g., pathogens) from

using their technology. In contrast, an individual using LexaGene's technology may be able to load their own real-time PCR-assays onto the instrument and instantly they may have a powerful automated bio-detector at their disposal to do the work that previously could only be performed by a skilled molecular biologist. Management believes this feature may open up markets that are poorly serviced by competitor technologies.

The second unique feature is that the MiQLab is capable of processing a range of sample volumes. Larger volume processing allows for more reliable detection of low titer (i.e., count) pathogens. The ability of the MiQLab to process larger volume samples translates into more frequent identification of samples containing disease-causing pathogens, and it shortens the time-to-result for detecting low-titer pathogens growing in an enrichment broth. Although this is a capability tested at the Company, the already launched MiQLab with the associated sample preparation cartridges are not equipped to handle sample volumes greater than 1 ml. Additional research and development into adaptors for the current sample preparation cartridges and/or new sample preparation cartridges, with the associated fluidic script changes would be required to fully enable this unique feature.

### Targeted Markets

The Company is primarily focused on veterinary diagnostics, biologics contract manufacturing, human clinical diagnostics for COVID-19 testing and open access markets such as biothreat detection. For the first two markets, the Company is spending significant resources on developing and manufacturing validated reagents for the MiQLab System to detect high-value pathogens and targets. Validated assays can be sold at a premium and are expected to be an important source of revenue for the company.

#### *Veterinary Diagnostics Market*

There are approximately 77M dogs and approximately 58M cats in the United States,<sup>1</sup> and many pet owners spare no expense on caring for their animal companions. The veterinary diagnostics market is expected to reach USD \$4 billion by 2023 from USD \$2.63 billion in 2018, at a CAGR of 8.8%.<sup>2</sup> Within this market, LexaGene is currently focusing on companion animal diagnostics, although the Company sees value in large animal testing, including the equine market.

LexaGene's own market research<sup>3,4</sup> has determined there are between 1,900 and 2,800 Emergency and Critical Care and Specialty Medicine hospitals for companion animals in the United States. These hospitals are open 24/7 and staff at least 5 veterinarians, making them an ideal target for further adoption of MiQLab System. Beyond this, there are roughly 18,600 veterinary clinics that have 5 employees and may be interested in using the MiQLab technology to quickly detect if infections are present a short time after the initial consultation, giving veterinarians more confidence in their prescribed treatment plan and ultimately leading to better patient outcomes.

At the request of the Company, Ethos Veterinary Health Group completed a market survey that confirmed the need for higher quality, point-of-care molecular diagnostics in the veterinary market. Ethos also provided a stack-rank list of pathogens and drug resistant targets that are of most interest to veterinarians. This survey information and from dialog with Ethos' veterinarians has guided the Company's product development decisions in veterinary health.

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<sup>1</sup> <https://www.avma.org/resources-tools/reports-statistics/us-pet-ownership-statistics>

<sup>2</sup> [https://www.marketsandmarkets.com/Market-Reports/veterinary-diagnostics-market-26017452.html?gclid=Cj0KCQiAmL-ABhDFARIsAKywVadtW6CcGzAM4imVPIgD\\_k64rwiIGNYmvp7GgNdab\\_DGMN9rII\\_KeeQaAnoREALw\\_wcB](https://www.marketsandmarkets.com/Market-Reports/veterinary-diagnostics-market-26017452.html?gclid=Cj0KCQiAmL-ABhDFARIsAKywVadtW6CcGzAM4imVPIgD_k64rwiIGNYmvp7GgNdab_DGMN9rII_KeeQaAnoREALw_wcB)

<sup>3</sup> U.S. Department of Labor, Census Bureau 2018

<sup>4</sup> <https://www.avma.org/sites/default/files/resources/2018-econ-rpt3-veterinary-services.pdf>

In emergency rooms and medical clinics, the MiQLab System has proven to identify disease-causing pathogen(s) and provide information on antibiotic resistance within ~ 2 hr. Veterinarians use this information to determine whether an infection is present, and if so, whether antibiotic resistance factors are present that might sway their prescription choice. Current tests for antibiotic resistance rely on lab tests that require 1-3 days, meaning that any antibiotics initially prescribed prior to obtaining test results may have no effect.

LexaGene is working on validating assays to target common veterinary pathogens, with an initial focus on pathogens that cause urinary tract infections and soft tissue infections. The Company's first panel for veterinary diagnostics is called the Bacterial and AMR panel. It includes tests for *E. coli*, *Proteus*, *Klebsiella*, *Enterobacter*, *Pseudomonas*, *Staphylococcus*, *Streptococcus* & *Enterococcus* and for bacteria and assays for the following antibiotic resistance genes for extended spectrum beta lactamases (CMY, CTX-M-1, CTX-M-9, SHV, and TEM), Methicillin resistance (*mecA*), Lincomycin/Clindamycin resistance (*erm A/B/C*), Sulfonamide resistance (Sul 1/2/3), Gram negative Trimethoprim resistance (*drfA* (14/5, 1/15, 17/7, 12)), Gram positive Trimethoprim resistance (*drfB E/F/G/K*), and Tetracycline resistance (*tet* (A, B, C, D, K, L, M, S, 38)). Antimicrobial resistance tests have also been developed for vancomycin resistance (*VanA* & *VanB*), and carbapenemase resistance (*KPC*, *VIM*, *IMP*, *NDM*, and *OXA48*).

In July 2021, LexaGene launched its second-generation bacterial and AMR panel. The new panel screens for 10 pathogens and 33 genes and variants that confer antimicrobial drug resistance. This represents an increase of 140% in pathogen testing and 270% in gene and variants testing compared to the first-generation test.

### Veterinary Competitors

For veterinary diagnostics, LexaGene is largely competing against reference laboratories such as IDEXX and Zoetis, as well as smaller organizations such as the Animal Health and Diagnostics Center at Cornell University, UPenn School of Veterinary Medicine, College of Veterinary Medicine, the UC Davis School of Veterinary Genetics Laboratory, among many others, which offers off-site testing services. These reference laboratories generally plate samples out across three types of plates for overnight growth (~ 12 – 18 hrs). Blood agar plates allow for total colony count, MacConkey plates selectively allow for gram negative growth, and Columbia CNA plates selectively allow for gram positive growth. Following plating, one or more colonies are selected and processed by a mass spectrometry (MALDI-TOF) (e.g., bioMérieux Vitek MS) for bacterial identification. For sensitivity testing, a colony is loaded into a card for incubation (19 – 24 hrs) and later fluorogenic reading (e.g., bioMérieux Vitek2). For this instrument, there are sensitivity cards for Gram +, Gram -, and *Streptococcus* strains. Reference laboratories typically are able to provide test results in ~ 3 days, but sometimes it takes longer.

Alternatively, urine can be plated on an antimicrobial susceptibility test plate (CCSP), such as the Flexicult® Vet Urinary Test, marketed by SSI Diagnostica. This test is currently not licensed for sale in the United States. CCSP technology requires ~24 hrs for test results, and need to be manually interpreted, introducing the possibility for reader-error.

Lastly, although mostly just used in human clinical diagnostics, there are dipstick assays with pads for protein, blood, leukocyte, nitrite, glucose, ketone, pH, specific gravity, bilirubin, and urobilinogen. Markers that can be used to identify urinary tract infections include nitrites, leukocyte esterase and blood. Individually, the sensitivities for blood, leukocyte esterase, and nitrite markers were found to be 64%, 49%, and 23%, respectively, when compared to culture-based analysis.<sup>5</sup> Due to the poor positive predictive value of these tests, they are seldom used.

Some reference laboratories may use a series of instruments to purify the genetic material within samples and assemble a series of PCR tests to screen for causative pathogens and antimicrobial resistance markers. These tests are more expensive due to the labor and higher costs of test reagents. Accordingly,

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<sup>5</sup> Mambatta et al., J Family Med Prim Care. 2015 Apr-Jun: 4(2): 265-268.

only a few labs use genomics for testing. LexaGene's MiQLab System automates the entire genomic testing workflow, lowering the barrier for labs to adopt PCR-based diagnostics.

### Veterinary Regulations

LexaGene is communicating with the United States Department of Agriculture's (USDA) Center for Veterinary Biologics (CVB) to receive licensure so it can begin to market and sell its products into the veterinary hospitals in the United States. LexaGene may first submit data to the USDA for *E. coli* testing. LexaGene may be required to determine the sensitivity and specificity of its *E. coli* assay and the repeatability and reproducibility of the assay with the associated master mix. CVB generally inspects a manufacturer's facility prior to commercial sales.

### Biologics Contract Manufacturing Organizations (BCMO) and Contract Drug Manufacturing Organizations (CDMO)

BCMOs and CDMOs make the vast majority of drugs, biologics and vaccines for human and animal health for pharmaceutical companies. These are often manufactured in bioreactors that can become contaminated, resulting in significant financial loss for the manufacturer and any contaminated product represents a health risk for patients and potential liability for the manufacturer. LexaGene has already sold its technology into this market and is further exploring how its technology can help meet the microbiological quality control (**QC**) needs for this industry. Traditionally, this industry uses culture for testing, but some of the contaminants may take weeks for detection and this time delay can be very costly. The industry is increasingly turning to automated Polymerase Chain Reaction (**PCR**) testing due to its sensitivity and speed with the expectation that new technology adoption may offer several benefits: a) more rapid process turnover, b) faster and safer product release, and 3) lower overall manufacturing costs. LexaGene's recent sale into this industry is a positive sign that the industry is primed for technology adoption. LexaGene demonstrated that the MiQLab System can detect bacteria including slow growing bacteria such as *Cutibacterium acnes* (**C. acnes**) which is one of the more common contaminants in bioreactors.<sup>6,7</sup> The time advantage for using MiQLab versus culture is expected to minimally be 36-times faster than culture, and possibly as much as 168-times faster.

The MiQLab System has the capabilities to help minimize the impact of *C. acnes* on product stability and conformity through rapid testing. Rapid testing is needed during each of the four main phases of manufacturing, including testing: the raw materials that go into bioreactors, the seed cultures before transfer to a bioreactor, the small bioreactor material being scaled up to a larger bioreactor, and the final product prior to sending it to the customer. Quickly identifying contamination during each of these steps minimizes profit losses that are often assumed and built-in to cost estimates for the manufacturer. Better testing also gives the manufacturer more confidence in meeting their delivery timelines for the customer.

We anticipate the industry using our technology to screen the raw materials going into bioreactors, test in-progress samples, and confirm finished products are free of contamination, which is a United States Food and Drug Administration (**FDA**) requirement. The manufacturing of biologics and vaccines is largely consolidated into very large, international companies that generate billions in revenue. Each company often has many manufacturing plants that could easily purchase multiple systems from LexaGene to help with their testing needs across all their products being manufactured on a daily basis. The biologics is a fast,

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<sup>6</sup> Lange-Asschenfeldt, B, D Marenbach, C Lang, A Patzelt, M Ulrich, A Maltusch, D Terhorst, E Stockfleth, W Sterry, and J Lademann. 2011. "Distribution of Bacteria in the Epidermal Layers and Hair Follicles of the Human Skin." *Skin Pharmacology and Physiology* 24 (6): 305–11.

<sup>7</sup> Salaman-Byron, Angel L. 2020. "Probable Scenarios of Process Contamination with *Cutibacterium* (*Propionibacterium*) *Acnes* in Mammalian Cell Bioreactor." *PDA Journal of Pharmaceutical Science and Technology* 74 (5): 592–601.

growing sector in BCMOs and CDMOs, projecting to grow at a compound annual growth rate (CAGR) of 9.06% from 2021 to 2026.<sup>8</sup>

### Human Clinical Diagnostic Market

In regards to human clinical diagnostics, also referred to as the *in-vitro* diagnostics market (IVD), LexaGene is pursuing FDA Emergency Use Authorization (EUA) for COVID-19 testing. This is a change in course for the Company, as it was originally planning on postponing pursuing the IVD market until after first succeeding in veterinary diagnostics and food safety testing. A brief recap of the course of events that led to this change in direction is provided below.

In December 2019 in Wuhan, China, there were several cases of severe unexplained pneumonia. On January 11, 2020, Chinese officials determined the cause of the infections was due to a novel coronavirus. On January 31, 2020, the United States Health and Human Services Secretary, Alex Azar, declared a public health emergency for SARS-CoV-2 and on February 4, he issued a Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19. This declaration provided liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act.

On February 5, the CDC test was granted Emergency Use Authorization (EUA) to allow for the marketing and sale of its COVID-19 test kit. Unfortunately, the kit was plagued with quality problems, preventing its use. Revising and getting the kits manufactured took weeks. After significant pressure from the Association of Public Health Laboratories and other public health officials, on February 29, FDA Commissioner Stephen M. Hahn, M.D. relaxed the FDA's policies, allowing for reference laboratories to start using their own COVID-19 diagnostic tests prior to receiving EUA. Also, under the EUA rules, test kit manufacturers were allowed to start selling COVID-19 tests into the clinical diagnostics market without having FDA 510(k) clearance. In late February, the Company's management met to discuss entering the COVID-19 testing market and decided it was in the best interest of the company to do so.

As of the writing of this document, over 700,000 American lives have been lost due to COVID-19.<sup>9</sup> By 2025, COVID-19 Diagnostic Kits and Therapy Market is expected to reach \$13.9 billion in value.<sup>10</sup> Although the Company's management feels morally obligated to pursue COVID-19 testing to help save lives, clearly there is a financial incentive as well.

On October 25, 2021, the Company announced that it completed analytical studies for FDA EUA of COVID-19 testing. The Company is in the process of completing the necessary work to have the FDA rule on authorizing MiQLab for COVID-19 testing. There is no guarantee that the FDA may grant the Company EUA for COVID-19 testing.

LexaGene originally planned to seek FDA EUA for COVID-19 testing in high complexity reference laboratories since the required studies are considerably less onerous than the studies required to have a diagnostic authorized for point-of-care (POC) use. The original plan was to pursue high complexity reference laboratory testing, and while the application was in review, start on the studies for POC use. However, the FDA has indicated that the POC submissions are being prioritized for review and the Company has heard anecdotal stories from other vendors seeking EUA for use in reference laboratories, but their applications have not been reviewed despite several months gone by. This delay may be due to these applications being for antibody-based technologies, which are given the lowest priority. Nonetheless, given the apparent delay in reviewing reference laboratory submissions and the fact that LexaGene's

<sup>8</sup> <https://www.mordorintelligence.com/industry-reports/biologics-market>

<sup>9</sup> [https://covid.cdc.gov/covid-data-tracker/#cases\\_casesper100klast7days](https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days)

<sup>10</sup> <https://www.marketwatch.com/press-release/covid-19-diagnostic-kits-and-therapy-market-to-reach-139-billion-by-2025--exclusive-report-by-meticulous-researchr-2020-06-19>

technology is designed for POC use, the Company decided to start the studies required for POC testing, even though these studies may take more time to complete.

Should LexaGene be successful in getting its technology through the FDA for EUA POC COVID-19 testing, the Company will be able to sell into ~ 193K locations certified to run POC tests, in contrast to only ~ 17K high complexity reference laboratories.<sup>11</sup> According to one market research firm, global COVID-19 diagnostics market size is estimated at USD \$96.3 billion by 2027 and is expected to expand at a compound annual growth rate (CAGR) of 6.28% from 2021 to 2027.<sup>12</sup> These predictions appear to assume that COVID-19 becomes a persistent endemic global threat that continuously mutates and may evade some vaccines. Although the ultimate resolution of COVID-19 remains unclear, the difficulty of reaching even 50% full vaccination in the US at this time increases the likelihood that the need for domestic and global COVID-19 testing will remain for some time.

### Human Diagnostic Industry

LexaGene's value is in multiplex testing for numerous pathogens at once (i.e., syndromic testing). Respiratory distress can be caused by many pathogens, not just SARS-CoV-2. However, the FDA's current EUA is for COVID-19 testing only. Other manufacturers of sample-to-answer multiplex diagnostics that have already been granted EUA for COVID-19 testing had already gone through the FDA 510(k) path for their syndromic testing technology so adding COVID-19 was a relatively easy task. LexaGene does not have the benefit of already going through the FDA for pathogen testing.

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain COVID-19 (or SARS-2 Coronavirus) at this time, nor that any of the Company's current COVID-19 diagnostic assays may be able to successfully detect all future SARS-2 Coronavirus variants that may emerge without re-design and validation.

### Human Diagnostic Competitors

In the human clinical diagnostics market, LexaGene may compete against some very large companies that are well funded and well established. Some of the competitors are Abbott Labs, Bayer, Becton Dickinson, bioMérieux, C-Diagnostics, Danaher, Eli Lilly, Grifols, LabCorp, OPKO Health, Quest Diagnostics, Roche Holdings, and Thermo Fisher Scientific.<sup>13</sup> Most of these companies offer solutions to reference laboratories that allow them to batch process many samples at once. Other companies, namely, GenMark, bioMérieux (BioFire), Luminex, Qiagen, Abbott, Danaher (Cepheid), Bosch, Mesa Biotech, and Quidel, to name a few, offer point-of-need testing instruments, which may directly compete against LexaGene's technology. Some of LexaGene's competitors market point-of-care tests that look for only coronavirus, are small, inexpensive, and extremely fast (e.g., 30 minutes or less). These platforms are not capable of highly multiplexed syndromic testing, nor do they perform as rigorous a sample prep, which is required for detecting some pathogens such as gram-positive bacteria and fungal pathogens. As such, these platforms have limited use in overall diagnostics compared to LexaGene's highly multiplexed MiQLab System that includes integrated high quality sample preparation.

### Food Safety Market

The Company's pursuit of FDA EUA for COVID-19 testing has forced the company to push back plans to enter the food safety market until sufficient capital is raised to apply resources towards this market. Nonetheless, it is a market the Company is very interested in pursuing. By 2025, the food safety market is

<sup>11</sup> [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/cert\\_type.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/cert_type.pdf)

<sup>12</sup> <https://www.medgadget.com/2021/02/covid-19-diagnostics-market-size-worth-96293-million-6-28-cagr-by-2027.html>

<sup>13</sup> <https://www.fool.com/investing/2020/04/07/here-are-all-the-companies-working-on-covid-19-vac.aspx>

expected to reach \$23.2 billion in value with a CAGR of 7.3% from 2018 - 2025.<sup>14</sup> This is attributed to the growth in demand for convenience and packaged food products, an increase in outbreaks of chemical contamination in food processing industries, and the rise in consumer awareness about food safety.<sup>15</sup> Despite the amount of testing, 48.8 million cases of foodborne illnesses occur per year in the United States, resulting in 127,000 hospitalizations and greater than 3,000 deaths. The economic impact of foodborne illnesses on the US economy is estimated to be ~ \$51 billion per year.<sup>16</sup>

The food testing industry is rapidly transitioning away from culture and adopting rapid testing. According to Bob Ferguson's recent Food Safety Insights column in Food Safety Magazine, in North America, 4 percent of testing is done by traditional culture-based methods only, 2 percent by chromogenic color-based visualization, 51.5 percent by antibody/immunoassay methods and 42.9 percent by molecular DNA-based methods.<sup>17</sup> Frequently, the chromogenic, antibody/immunoassay tests, and DNA-based tests are performed after a culture has reached stationary phase. Generally speaking, the food safety industry processes lots of samples per day, but the cost per processed sample is generally lower than in other markets.

For foodborne illnesses that can be tied back to a food product, the U.S. Food and Drug Administration ("FDA") and USDA generally require the food producer to recall the product. On average, the FDA recalls 48 meat products per year, equating to roughly 26.8 million pounds of meat.<sup>18</sup> Recalls can cost the food producer 10's of millions of dollars and irreparable damage to brand name.

### LexaGene's Value Proposition for the Food Industry

LexaGene expects to first market its technology to screen perishable ready-to-eat products, since time (shelf life) is critical for these items. Due to the very low titer of bacteria expected in the food industry, sample enrichment via culture is often considered a requirement. That said, LexaGene's management feels that when dealing with an enriching sample, time-to-result can be shortened by processing a larger volume of the enrichment broth, thereby minimizing the possibility of subsampling error.

LexaGene's technology is ideally suited for this since it is capable of concentrating the bacteria in larger volumes of enrichment media than conventional technologies, as its sample preparation cartridge is designed to capture bacteria on a filter prior to lysis. This is anticipated to minimize sub-sampling error, which in turn is expected to allow for shorter culture times prior to genetic testing. Saving just a few hours can result in significant cost savings for larger processors, who maintain inventory distribution centers maintained at 4°C. As previously mentioned, LexaGene current sample preparation cartridge is only able to process ~ 250 µL of sample, so additional research and development may be required to build a sample preparation cartridge that is specifically designed to process larger sample volumes to achieve this benefit.

LexaGene has already validated tests for *E. coli* 0157, H7, O111, shiga toxin-1&2, salmonella, and listeria spp.

### Food Safety Regulations

The FDA passed the *Food Safety Modernization Act* ("FMSA") in 2010, which gave the FDA the power to mandate a science-based system to address the hazards from farm-to-table and regulate testing

<sup>14</sup><https://www.alliedmarketresearch.com/food-safety-testing-market#:~:text=The%20global%20food%20safety%20testing%20market%20size%20was,for%20disease-causing%20organisms%2C%20chemicals%2C%20and%20other%20hazardous%20materials>

<sup>15</sup> <https://www.marketsandmarkets.com/PressReleases/food-safety-testing-market.asp>

<sup>16</sup> Scharff, R.L., Economic burden from health losses due to foodborne illness in the United States. J Food Protection, 2012. 75(1): 123-131.

<sup>17</sup> <https://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2017/the-drivers-of-differences-in-food-safety-testing-practices/>

<sup>18</sup> <http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-summaries>

procedures. The FDA regulates beverages, fruits, vegetables, seafood, and most other food items, while the USDA regulates meat, poultry, eggs products, and catfish.

In 2015, the FDA announced the FMSA testing and reporting requirements, which are to be rolled out and enforced between 2016 – 2018.<sup>19</sup> Implementing and enforcing some requirements have been delayed. Before these requirements were put into place, food producers were only required to respond to an outbreak by initiating a food recall. The policy was very 'reactionary' rather than being 'pro-active' to prevent disease from occurring in the first place. Under the new FMSA policy, some food producers may now be required to test their products, verifying they are free of disease-causing pathogens, prior to shipment. The FDA may also inspect at least once per three years rather than once per decade. Auditors may also have the authority to inspect foreign food suppliers.

To meet testing requirements set out by the USDA and FDA, food producers greatly favor using technologies that are certified by the Association of Official Analytical Chemists ("AOAC"), although many food producers may accept a technology publication as proof of sufficient quality testing for use on their products.

Once LexaGene launches a product into the food safety industry, it anticipates its technology to be used in the screening process of enriched broths to rapidly and accurately assess the risk level of contamination for food and beverage items. This may allow food safety officers to more quickly clear their products for delivery to customers. The company also expects LexaGene's technology to be used for environmental sampling of food processing and storage facilities, where often culture is skipped and direct genetic testing is now viewed as acceptable.

### Food Safety Competitors

Food producers and processors are under enormous pressure to provide safer and fresher food and beverage items. LexaGene knows of no other company that provides easy to use automated highly-multiplexed molecular genetic testing in the food safety market. Currently, the food industry relies on either food plant laboratories (on-site) or food contract laboratories (off-site) for testing services. At these laboratories, samples are added to enrichment media to provide conditions for viable bacteria to multiply for 24+ hours prior to removing a portion of the culture for rapid testing, either using antibody-based technologies, genetic amplification tests by PCR or isothermal methods, or other chromogenic or fluorogenic tests.

The companies currently providing testing reagents for the food industry include: Bio-Rad Laboratories, Agilent, ALS Food & Pharmaceutical, Bureau Veritas, BioControl Systems, bioMérieux, Eurofins Scientific, Genevac Ltd, Genon Laboratories, Neogen, IDEXX Laboratories, Intertek Group, SGS, Thermo Fisher Scientific, Dupont Nutrition and Health, and many others.

For automated molecular testing, one of LexaGene's biggest competitors is RokaBio, Inc., which is a wholly-owned subsidiary of Institute for Environmental Health, Inc. ("IEH").

### Open-Access Markets

The Company views this market as any group wanting a customized, multiplex, PCR reaction test in liquid sample form for collections of pathogenic organisms harmful or important to their industry. Industries that potentially have a need for a technology that automates PCR includes, but is not limited to contract manufacturers, pharmaceutical, academic, and government laboratories, as well as laboratories performing water quality testing, aquaculture pathogen surveillance, and genotyping. LexaGene believes there is a need for open-access technology that allows for automated sample preparation integrated with highly multiplexed PCR, but the scale of the demand for such a technology in these industries is uncertain since

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<sup>19</sup> <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

it is a novel capability. The size of the open-access market is hard to estimate since no formal market assessments have been published.

## OPERATIONAL HIGHLIGHTS

### For the six months ended August 31, 2021

On March 2, 2021, LexaGene announced it received \$3.6M from the exercise of warrants.

On April 14, 2021, LexaGene hosted a seminar presenting data from using the MiQLab System on veterinary samples. At this seminar, the Company announced that the MiQLab is sensitive enough to detect the vast majority of clinical infections caused by target organisms. The MiQLab was ~100% positive percent agreement with culture data on processed canine urine samples, ~99% negative percent agreement with culture data on processed canine urine samples, ~99% overall percent agreement with culture data on processed canine urine samples, the MiQLab detected *Staphylococcus* in 21 of 23 (91%) specimens from skin infections in a correlation study, detected the *mecA* gene in 8 of 9 (89%) specimens that contained methicillin resistant *Staphylococcus* and had quantitative data on par with culture ( $r^2 \sim 0.95$ ).

On May 11, 2021, the Company announced that it expanded its sales team by hiring four additional sales representatives, including three representatives for the veterinary market and one representative serving the Biologics Contract Manufacturing Organizations and Contract Drug Manufacturing Organizations.

On June 1, 2021, LexaGene announces that it is taking steps to list its common shares on the Nasdaq Capital Market with the goal of submitting its application prior to the end of 2021. LexaGene has reserved with the Nasdaq Exchange the ticker symbol LXG, which is good for 24 months.

On June 3, 2021, LexaGene announced it partnered with Ethos Discovery to develop tests for pneumonia and diarrhea panels to be used on the MiQLab System.

On June 10, 2021, LexaGene announced that its MiQLab System could detect *C. acnes*, a slow-growing bacterium found in bioreactors at least 36-times faster than other conventional methods with the potential to increase vaccine safety and supply.

On June 17, 2021, the Company announced that its MiQLab System offers rapid plague detection for bioterrorism threats.

During the month of June, the Company had three press releases that announced the closing of three MiQLab System sales to Denver Animal Emergency in North Carolina, Alpine Veterinary Hospital in California and with Meridian Veterinary Real Estate in Texas. Meridian purchased their unit on behalf of its emergency specialty veterinary hospitals.

On July 2, 2021, the Company announced it continues to systematically advance the MiQLab System to meet the Food and Drug Administration (FDA) criteria for Emergency Use Authorization (EUA).

On July 7, 2021, LexaGene announced the launch of its second-generation assay panel to improve coverage for pathogens that cause common types of infections, namely skin, soft tissue, wound and ear infections. LexaGene's first Bacterial and AMR Test screened samples for 7 different pathogens and 13 different antimicrobial resistance factors. This first panel was largely built around pathogens and resistance genes commonly encountered in urinary tract infections (UTIs), and was well received within the veterinary community. LexaGene's second-generation assay panel, taking advantage of the platform's capacity for new targets, was expanded at the request of veterinarians to improve coverage for pathogens that cause other common types of infections, namely skin, soft tissue, and wound infections (SSTIs), and ear infections.

LexaGene's Bacterial and AMR Test Version 2 (V2) screens for 10 pathogens and 33 genes and variants that confer antimicrobial drug resistance. The AMR Test Version 2 (V2) detects 96 percent of bacterial UTIs

and 93 percent of bacterial SSTIs, and detect a much higher percentage of genes that confer resistance to some of the most commonly prescribed antibiotics.

On July 14, 2021, the Company announced its strategic partnership with Wolf Greenfield, an intellectual property (IP) law firm specializing in patents, licensing and royalty transactions, post-grant proceedings, and trademark and copyrights.

On July 20, 2021, LexaGene announced its MiQLab detecting common bioreactor contaminants up to 300 times faster than conventional methods. The MiQLab System can detect the presence of mycoplasmas, a group of common microbial contaminants responsible for substantial losses in both time and money for biopharmaceutical manufacturers. Mycoplasmas are thought to contaminate 15-80% of cell cultures worldwide. The MiQLab System rapidly detected 100% of the tested mycoplasma samples within two hours, with no false positives. The MiQLab can be used inside biopharmaceutical manufacturers to rapidly validate their products as being free and clear of mycoplasmas.

On August 12, 2021, the Company announced that it demonstrated simple, inexpensive multiplex PCR chemistry with shorter lead times for use on its MiQLab System. In a small study, MiQLab successfully detected both *Escherichia coli* and an internal amplification control using SYBR Green chemistry.

### **Subsequent to August 31, 2021**

On September 6, 2021, the Company filed Preliminary Short Form Base Shelf Prospectus ("Shelf Prospectus") with the securities regulators in each of the provinces and territories of Canada. The Shelf Prospectus is effective for 25 months and will allow the Company to raise up to CAD\$25 million through issuances of common shares, warrants, subscription receipts, debt securities, units or any combination thereof during the period it is effective.

On September 3, 2021, LexaGene announced that MiQLab accurately detected multiple strains of pathogenic bacteria in polymicrobial samples in approximately 2 hours. In comparison, Culture and Sensitivity Testing (C&ST) failed to detect the minor pathogen population in individual mixed samples, with final test results taking up to 11 days.

On September 16, 2021, the Company announced that it entered into a cooperative research and development agreement with the United States army's combat capabilities development command ("DEVCOM"). Under this agreement, LexaGene will deliver MiQLab systems to DEVCOM for the purpose of determining the system's ability to detect *Bacillus anthracis* and *Yersinia pestis*, which cause anthrax and plague, respectively. DEVCOM will determine the system's sensitivity (e.g., limit-of-detection) for these two pathogens as well as evaluate the system's quantitative detection capability.

On September 17, 2021, the Company adopted new corporate governance charters and policies, which include a new audit committee charter, a compensation committee charter, a nominating and corporate governance charter, a cyber security policy, and a code of business conduct and ethics. The Company also filed a Final Base Shelf Prospectus, which allows the Company to offer up to \$25 million of common shares, warrants, subscription receipts, debt securities or units or any combination thereof, from time to time during the 25-month period that the Shelf Prospectus is effective.

In September, LexaGene participated in veterinary trade shows, including WVC 93rd Annual Conference in Las Vegas, NV, International Veterinary Emergency and Critical Care in Nashville, TN, and Southwest Veterinary Symposium in San Antonio, TX.

LexaGene announced its participation in the key investor conferences in early October, including BioFuture 2021, October 5-6, Lytham Partners Fall 2021 Investor Conference, October 5-7, and Small Cap Growth Virtual Investor Conference, October 7.

On October 7, 2021, LexaGene announced that its largest study validated the accuracy of its veterinary test panel. The Company successfully utilized its MiQLab System to correctly identify bacteria and

determine the presence of antimicrobial resistance markers that predict resistance to commonly prescribed first-line veterinary antibiotics. The study used two sets of bacterial pathogens. The first set consisted of 32 sequenced strains from the CDC Antibiotic Resistance Isolate Bank.<sup>20</sup>The second set included 74 bacterial isolates from dogs with urinary tract infections. These isolates were not sequenced and have only culture-based drug resistance profiles associated with them.

MiQLab Systems, equipped with MiQLab Bacterial and AMR Test V2 panels, recorded 100% and 99.1% overall percent agreements for pathogen identification for the sequenced CDC pathogens and the non-sequenced canine UTI isolates, respectively. Likewise, the MiQLab recorded 96.2% and 92.5% overall percent agreements for antimicrobial resistance for the sequenced CDC pathogens and non-sequenced canine UTI isolates for which only culture data is available, respectively. An in-depth version of these data is being compiled for a peer-reviewed publication.

On October 25, 2021, the Company announced that it completed analytical studies required by the FDA for EUA application for COVID-19 diagnostics. LexaGene is in the process of completing the necessary work to have the FDA rule on authorizing the MiQLab™ for COVID-19 testing. The FDA is expected to classify the MiQLab as a class II medical device. As such, the process of preparing its point-of-care (POC) fully-automated PCR system, which is comprised of hardware, firmware, software, and chemistry, for evaluation by the FDA, is considerably more complex than if it were simply submitting only a COVID-19 PCR test chemistry for FDA authorization.

## SELECTED YEARLY INFORMATION

	February 28, 2021	February 29, 2020	February 28, 2019
Total assets	\$ 13,194,700	\$ 5,988,821	\$ 1,703,886
Working capital	\$ 10,096,770	\$ 2,940,002	\$ 622,565
Non-current liabilities	\$ 1,289,058	\$ 1,606,015	\$ -
Revenues	\$ 58,125	\$ -	\$ -
Loss for the year	\$ (9,891,015)	\$ (7,499,163)	\$ (8,321,374)
Loss per share	\$ (0.10)	\$ (0.10)	\$ (0.13)

<sup>20</sup> Antibiotic Resistance Isolate Bank. Atlanta (GA): CDC. <https://wwwn.cdc.gov/arisolatebank/>

**SELECTED QUARTERLY INFORMATION**

The following selected financial data has been prepared in accordance with IFRS and should be read in conjunction with the Company's financial statements. All dollar amounts are in United States dollars.

Quarter ended	Revenue for the period	Net loss for the period	Net loss per share (basic & diluted)	Total assets
August 31, 2021	\$ 40,625	\$ (2,816,320)	\$ (0.02)	\$ 8,058,614
May 31, 2021	\$ -	\$ (2,711,785)	\$ (0.02)	\$ 10,802,223
February 28, 2021	\$ 58,125	\$ (2,357,481)	\$ (0.03)	\$ 13,194,700
November 30, 2020	\$ -	\$ (2,981,146)	\$ (0.02)	\$ 12,259,212
August 31, 2020	\$ -	\$ (2,108,246)	\$ (0.02)	\$ 5,806,205
May 31, 2020	\$ -	\$ (2,444,142)	\$ (0.03)	\$ 4,947,441
February 29, 2020	\$ -	\$ (1,679,470)	\$ (0.03)	\$ 5,988,821
November 30, 2019	\$ -	\$ (2,530,693)	\$ (0.02)	\$ 5,749,225

**RESULTS OF OPERATIONS****Three months ended August 31, 2021 compared to the three months ended August 31, 2020***Revenue*

During the three months ended August 31, 2021, the Company recognized revenue of \$40,625 in connection with the sale of two MiQLab Systems and consumables.

*Net loss*

For the three months ended August 31, 2021, the Company recorded a net loss of \$2,816,320 compared to a net loss of \$2,108,246 for the three months ended August 31, 2020. The net loss increased for the three months ended August 31, 2021 in comparison to the same period in 2020. This increase of \$708,074 was due to the following items:

*Cost of product expenses*

During the period ended August 31, 2021, the Company incurred an expense of \$132,883 in relation to MiQLab product line as compared to \$Nil in the same period of 2020. The increase was related to the cost of MiQLab Systems sold during the period in the amount of \$38,357 and manufacturing costs of \$94,526. As there were no sales during the same period of 2020, no similar costs were incurred.

*Operating expense*

The total operating activities for the three months ended August 31, 2021, resulted in an expense of \$2,733,585 as compared to an expense of \$2,108,246 for the same period in 2020. This increase of \$625,339 is primarily the result of the following items:

*Sales, marketing and promotional expense*

Comparing the three months ended August 31, 2021, to the same period in 2020, marketing and promotional expenses increased to \$566,905 from \$376,064. This increase of \$190,841 in marketing and promotional expenses are primarily from the following items:

- Salaries and wages associated with marketing and promotional activities increased to \$392,981 for the three months ended August 31, 2021, as compared to \$192,119 for the same period in 2020. This increase of \$200,862 in expense to salaries and wages is directly related to the increase in head count year over year.

- As a result of vesting of an increase in the number of options and RSUs granted in prior periods and increase in the head count compared to 2020, share-based compensation expense increased by \$11,074 for the three months ended August 31, 2021.
- LexaGene is committed to building its brand and promoting its MiQLab technology in multiple markets. General marketing, advertising and promotional expenses decreased to \$134,774 for the three months ended August 31, 2021, from \$154,755 for the same period in 2020. This decrease of \$19,981 is due to the timing of expenses.

#### *General and administrative expenses*

Comparing the three months ended August 31, 2021, to the same period in 2020, general and administrative expenses increased to \$565,920 from \$462,856. This increase in expense of \$103,064 in general and administrative activities are primarily from the following items:

- Share-based compensation expense increased to \$189,808 in 2021, as compared to \$161,173 for the same period in 2020. This increase of \$28,635 is primarily related to vesting of the higher number of options and restricted share units previously granted to directors, employees and consultants, offset by reversal of share-based compensation related to unvested options that forfeited during the period.
- During the three months ended August 31, 2021, professional fees increased to \$96,312 from \$61,366 and transfer agent and filing fees increased to \$32,150 from \$9,790. The total increase of \$57,306 was primarily due to legal and assurance fees related to the filing of the Shelf Prospectus and review of the interim financial statements by the Company's independent auditor.
- During three months ended August 31, 2021, the Company recognized an expense of \$99,386 for promotion and investor relations in general and administrative expenses compared to \$53,858 during the same period in 2020. This increase of \$45,528 is related to the Company's attendance at trade show and conferences as well as continuing efforts promoting the Company and building brand awareness.

#### *Research and development expenses*

Comparing the three months ended August 31, 2021, to the same period in 2020, research and development expenses increased to \$1,600,760 from \$1,269,326. This increase in expense of \$331,434 in research and development activities are primarily from the following items:

- Salaries and wages increased to \$879,811 for the three months ended August 31, 2021 as compared to \$659,715 for the same period in 2020. This increase is the result of the Company adding to its headcount. Lower salaries and wages in the three months ended August 31, 2020, are also a result of the PPP Loan received during that period. See Government Grants section
- Share-based compensation increased to \$146,135 for the three months ended August 31, 2021, compared to \$(56,824) for the three months ended August 31, 2020. This increase is due to the increase in headcount and a higher number of awards vesting during 2021.
- Lab administration and supplies increased by \$110,567 from \$14,813 during the period ended August 31, 2020 to \$125,380. This increase was due to the Company's efforts expanding its menu offerings of tests for both veterinary diagnostics and contract drug biologics.
- Product development consulting expense decreased to \$7,440 during the period ended August 31, 2021, compared to \$196,498 in the same period of 2020. The decrease of \$189,058 is due to the Company increasing the head count and reducing reliance on external engineering and consulting firms.

***Six months ended August 31, 2021 compared to the six months ended August 31, 2020****Revenue*

During the six months ended August 31, 2021, the Company recognized revenue of \$40,625 in connection with the sale of two MiQLab Systems and consumables.

*Net loss*

For the six months ended August 31, 2021, the Company recorded a net loss of \$5,527,913 compared to a net loss of \$4,552,597 for the six months ended August 31, 2020. The net loss increased for the six months ended August 31, 2021 in comparison to the same period in 2020. This increase of \$975,316 was due to the following items:

*Cost of product expenses*

During the period ended August 31, 2021, the Company incurred an expense of \$227,797 in relation to MiQLab product line as compared to \$0 in the same period of 2020. The increase of \$227,797 was because no MiQLab Systems were sold during the six-month period ended August 31, 2020 compared to units sold in 2021. The increase was comprised of the following items:

- Salaries, wages and manufacturing costs associated with cost of product of \$189,440 in 2021, as compared to \$0 for the same period in 2020.
- Costs of MiQLabs sold of \$38,357 compared to \$0 in 2020. These costs are made up of materials used to make the MiQLab Systems.

*Operating expense*

The total operating activities for the six months ended August 31, 2021, resulted in an expense of \$5,350,262 as compared to an expense of \$4,552,597 for the same period in 2020. This increase of \$797,665 is primarily the result of the following items:

*Sales, marketing and promotional expense*

Comparing the six months ended August 31, 2021, to the same period in 2020, marketing and promotional expenses increased to \$1,176,531 from \$682,183. This increase of \$494,348 in marketing and promotional expenses are primarily from the following items:

- Salaries and wages associated with marketing and promotional activities increased to \$775,982 for the six months ended August 31, 2021, as compared to \$309,324 for the same period in 2020. This increase of \$466,658 in expense to salaries and wages is directly related to the increase in head count year over year.
- LexaGene is committed to building its brand and promoting its MiQLab technology in multiple markets. As such, general marketing, advertising and promotional campaign expenses increased to \$377,815 for the six months ended August 31, 2021, from \$324,905 for the same period in 2020. This increase of \$52,910 is related to the Company's efforts promoting and supporting the commercial launch of the MiQLab System in both veterinary diagnostics and contract biologics manufacturing.
- This increase is offset by a decrease in share-based compensation expense by \$27,824 for the six months ended August 31, 2021, as compared to the same period in 2020. This decrease is due to a reversal of the previously recognized expense related to unvested options and RSUs that were forfeited.

### *General and administrative expenses*

Comparing the six months ended August 31, 2021, to the same period in 2020, general and administrative expenses increased to \$998,754 from \$987,062. This increase of \$11,692 in general and administrative activities is primarily from the following items:

- Increase in promotional services of \$30,076 compared to the same period of 2020. This increase of promotional services to \$146,264 was due to the increase in the number of promotional campaigns initiated by the Company during 2021 as compared to 2020.
- Transfer agent and filing fees increased from \$19,721 to \$38,564. This increase is a result of fees incurred in connection with the filing of the Shelf Prospectus.
- These increases are offset by a decrease in salaries from \$95,698 to \$72,125. The decrease of \$23,573 is due to changes in composition of staff.

### *Research and development expenses*

Comparing the six months ended August 31, 2021, to the same period in 2020, research and development expenses increased to \$3,174,977 from \$2,883,352. This increase of \$291,625 in research and development activities are primarily from the following items:

- Salaries and wages increased to \$1,813,054 for the six months ended August 31, 2021 as compared to \$1,313,232 for the same period in 2020. This increase is the result of the Company adding to its headcount. Lower salaries and wages in the six months ended August 31, 2020, are also a result of the PPP Loan received during that period. See Government Grants section
- Share-based compensation increased to \$245,212 for the period ended August 31, 2021, compared to \$(22,437) for the period ended August 31, 2020. This increase is due to the increase in headcount and the number of awards vesting during the period ended August 31, 2021 compared to 2020.
- Lab administration and supplies increased by \$283,377 from \$25,118 during the period ended August 31, 2020, to \$308,495. This increase was due to the Company's efforts expanding its menu offerings of tests for both veterinary diagnostics and contract drug biologics. This increase is offset by a decrease in materials from \$720,250 to \$618,579 as more materials are used for manufacturing MiQLab Systems in the current period.
- Product development consulting expense decreased to \$48,630 during the period ended August 31, 2021, compared to \$724,279 in the same period of 2020. The decrease of \$675,649 is due to the Company reducing reliance on external engineering and consulting firms. This decrease offset increases in research and development expenses during the six months ended August 31, 2021.

## **GOVERNMENT GRANTS**

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In May 2020, LexaGene received a loan under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security (CARES) Act in the amount of \$108,178 (the "**PPP Loan**"). The PPP Loan had a 2-year term with an annual interest rate of 1%. Monthly principal and interest payments were deferred for 10 months, and the maturity date on the PPP Loan was May 1, 2022.

The Paycheck Protection Program was a business loan program established by the United States Federal Government under the CARES Act to help businesses impacted by the COVID-19 pandemic allowing companies to continue paying employee and other special business expenses.

In accordance with IAS 20, LexaGene has recognized the \$108,178 PPP Loan proceeds received during the year ended February 28, 2021, in the consolidated statements of comprehensive loss and included as cash flows from financing activities in the consolidated statement of cash flows. The proceeds of \$108,178 were used to offset expenses for salaries and wages in general and administrative of \$14,255 and in research and development of \$93,923 during fiscal 2021.

During the 24-week forgiveness period in 2020, LexaGene used the full amount received to fund expenses under the terms of the PPP Loan. As a result, LexaGene submitted an application for forgiveness of the PPP Loan to the Small Business Administration ("SBA"). The SBA forgave the PPP Loan on March 16, 2021.

## FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

The Company's working capital at August 31, 2021 was \$5,451,750 including cash of \$4,221,299 compared to a working capital of \$10,096,770 including cash of \$9,624,259 as of February 28, 2021.

The Company's business currently does not generate positive cash flows from operations. At August 31, 2021, the Company had an accumulated deficit of \$39,792,793 since inception. The Company is reliant on equity financings to provide the necessary cash to continue the commercialization of the MiQLab System described in the Summary of Operations, and generating cash flow from operations in the future. These factors form a material uncertainty, which may raise significant doubt about the Company's ability to continue as a going concern.

## OFF-BALANCE SHEET ARRANGEMENTS

As of the date of this filing, the Company does not have any off-balance-sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Company, including, and without limitation, such considerations as liquidity and capital resources.

## RELATED PARTY TRANSACTIONS

Key management includes personnel having the authority and responsibility for planning, directing and controlling the Company and includes the directors and current executive officers. During the three and six months ended, August 31, 2021, and 2020, expenses incurred for key management compensation are summarized as follows:

	Three months ended August 31,		Six months ended August 31,	
	2021	2020	2021	2020
Salaries and benefits	\$ 249,237	\$ 174,436	\$ 519,193	\$ 360,497
Consulting fees	-	10,800	-	21,600
Stock-based compensation	209,790	160,088	394,971	366,537
	<b>\$ 459,027</b>	<b>\$ 345,324</b>	<b>\$ 914,164</b>	<b>\$ 748,634</b>

As of August 31, 2021, \$0 was payable to key management (February 28, 2021 - \$0).

There are no post-employment expenses or other long-term expenses for key management.

## RECONCILIATION OF USE OF PROCEEDS FROM FINANCING ACTIVITIES

On September 9, 2020, the Company issued 15,640,000 units at an offering price of \$0.65 (CAD\$0.85) per Unit for aggregate net proceeds to the Company of approximately \$10.1 million (CAD\$13.29 million). Each unit consisted of one common share and one –half of one common share purchase warrant. Each whole warrant entitles the holder to purchase, subject to adjustment in certain circumstances, one additional common share at a price of CAD\$1.10 per common share until September 9, 2023. The Company paid

approximately \$99,700 (CAD \$131,390) in finders and legal fees and granted 1,094,800 broker warrants exercisable at CAD\$1.10 until September 9, 2023.

At August 31, 2021, the use of proceeds is listed below and converted to US Dollars using the Canadian to US Dollar exchange rate of 0.7253:

Intended Use of Proceeds of September 9, 2020 Offering (CAD)	US Dollar Conversion (USD)	Actual Use of Proceeds from September 9, 2020 Offering (USD)	Variance (Over)/Under Expenditure (USD)	Explanation of Variance and Impact on Business Objectives	
<b>Salaries and benefits for:</b>	\$ 6,085,000	\$ 4,413,451	\$ 4,413,451	\$ -	Completed
- the current employees for one year					
- additional sales representatives, three additional veterinary sales representative and additional COVID-19 representatives					
- two customer service representatives					
- two to three inside sales representatives					
- two additional biologists					
<b>Implementation of CRM systems</b>	\$ 75,000	\$ 53,398	\$ 53,398	\$ -	Completed
<b>Implementation of quality control systems</b>	\$ 150,000	\$ 108,795	\$ 57,760	\$ 51,035	Ongoing
<b>Implementation of operational support systems</b>	\$ 25,000	\$ 18,133	\$ 8,000	\$ 10,133	Ongoing
<b>Purchase of inventory for commercial builds</b>	\$ 1,875,000	\$ 1,359,938	\$ 1,359,938	\$ -	Completed
<b>Purchase of equipment, biological reagents, consumable materials and tooling</b>	\$ 300,000	\$ 217,590	\$ 87,180	\$ 130,410	Ongoing
<b>Product development and manufacturing expenses</b>	\$ 750,000	\$ 543,975	\$ 229,229	\$ 314,746	Ongoing
<b>Product and corporate marketing campaigns</b>	\$ 840,064	\$ 609,298	\$ 613,891	\$ (4,593)	Completed
<b>General working capital purposes, investments in new systems, technologies and processes</b>	\$ 400,736	\$ 290,654	\$ 290,654	\$ -	Completed
<b>Total</b>	<b>\$ 10,500,800</b>	<b>\$ 7,615,232</b>	<b>\$ 7,113,501</b>	<b>\$ 501,731</b>	

At August 31, 2021, the cash remaining from this financing is \$501,731.

## FINANCIAL INSTRUMENTS

LexaGene is active in the life science industry, which means the Company is exposed to a number of risks. There is a financial risk as the continuing operations of the Company are dependent upon its ability to continue to raise adequate financing and to commence profitable operations in the future. The Company has incurred operating losses since its inception and has experienced negative operating cash flows.

### Fair Values

The fair values of cash, receivables and accounts payables approximate their book values because of the short-term nature of these instruments.

**(a) Financial Risk Management**

The Board of Directors has overall responsibility for the establishment and oversight of the Company's risk management framework. The Company considers the fluctuations of financial markets to be a risk and seeks to minimize the potential adverse effects on financial performance.

**(b) Financial Instrument Risk Exposure**

The Company is exposed in varying degrees to a variety of financial instrument related risks. The Board approves and monitors the risk management process.

*Credit Risk*

Credit risk is the risk of an unexpected loss if a third party to a financial instrument fails to meet its contractual obligations. The Company's cash is held at major United States and Canadian financial institutions. The Company considers credit risk on its cash to be minimal.

Credit risks associated with accounts receivable risk is the risk of a financial loss if a customer fails to meet its obligations under a sales contract. This risk primarily arises from the Company's receivables from customers. The Company regularly reviews the collectability of its accounts receivable and would establish an allowance account for credit losses based on its best estimate of any potentially uncollectible accounts receivables. On August 31, 2021, the balance of the allowance account for credit losses was \$0 (February 28, 2021 - \$0).

*Liquidity Risk*

Liquidity risk is the risk that LexaGene will encounter difficulty in satisfying financial obligations as they become due. The Company manages its liquidity risk by forecasting cash flows from operational needs and anticipated financing activities. The Company's objective in managing liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements. The Company's accounts payable and accrued liabilities have contractual maturities of less than 30 days and are subject to normal trade terms.

*Market risk*

Market risk is the risk of loss that may arise from changes in market factors such as interest rates, foreign exchange rates, and commodity and equity prices. Such fluctuations may be significant.

*(i) Interest rate risk*

The Company has no interest-bearing investments or debt other than the lease liability, which is subject to a fixed interest rate, and therefore is not subject to a significant interest risk.

*(ii) Foreign currency risk*

Currency risk is the risk that the fair values or future cash flows of the Company's financial instruments may fluctuate because of changes in foreign currency exchange rates. The Company is exposed to currency risk through financial assets and liabilities denominated in currencies other than the US dollar, the Company's presentation currency.

The Company's financial instruments denominated in currencies that are not the United States dollar as of August 31, 2021 are as follows:

	CAD\$		USD\$ Equivalent	
Cash	\$	2,971,793	\$	2,355,443
Accounts payable and accrued liabilities		(152,218)		(120,648)
Net exposure	\$	2,819,575	\$	2,234,795

The impact of a 5% change in the foreign exchange rates of the Canadian dollar against the US dollar (USD) on the financial assets and liabilities of the Company at August 31, 2021, is estimated to have an impact in the Company's loss (holding all other variables constant) in the amount of approximately \$112,000 (February 28, 2021 - \$329,000). The carrying amount of cash, accounts payable and accrued liabilities in USD represents the Company's exposure as of August 31, 2021.

*(iii) Price risk*

The Company is exposed to price risk with respect to commodity and equity prices. Equity price risk is defined as the potential adverse impact on the Company's earnings due to movements in individual equity prices or general movements in the level of the stock market. Commodity price risk is defined as the potential adverse impact on earnings and economic value due to commodity price movements and volatilities. The Company closely monitors commodity prices, individual equity movements, and the stock market to determine the appropriate course of action to be taken by the Company.

## RISK AND UNCERTAINTIES

An investment in the Company should be considered highly speculative due to the nature of its activities and the stage of its development. Diagnostic research and development involves a significant degree of risk. The risks and uncertainties set forth below are not the only ones we may face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business and operations and cause the price of the Common Shares to decline. If any of the following risks actually occur, our business may be harmed and our financial condition and results of operations may suffer significantly. In that event, the value of the Common Shares could decline and purchasers of the Common Shares or securities convertible into Common Shares may lose all or part of their investment. Readers should carefully consider the following risk factors in addition to the other information contained herein before investing in the Company.

Significant areas requiring the use of management estimates include:

*The valuation of inventory*

Raw materials, work in process, and finished goods inventories are stated at the lower of cost and net realizable value, with cost being determined using a weighted average costing formula. Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and the estimated costs necessary to make the sale. The Company maintains three categories of inventory: raw materials, work in process and finished goods.

*The useful lives of property and equipment*

The Company amortizes its property and equipment based on estimates of their useful lives. Changes in useful lives and depreciation rates of these assets may have a significant impact on amortization recorded in consolidated statement of comprehensive loss and value of corresponding property and equipment.

*The useful lives of the intangible assets*

Determination of useful lives of intangible assets involves judgment as it impacts amortization recorded in the consolidated statement of comprehensive loss. When the Company commenced research and development activities, the intangible assets began being amortized over 10 years upon the execution of the Agreement with Lawrence Livermore National Security.

*The valuation of share-based payments and warrants*

The Company uses the Black-Scholes Option Pricing Model for valuation of share-based payments. Option pricing models require the input of subjective assumptions including expected price volatility and forfeiture

rate. Changes in the input assumptions can materially impact fair value estimates and the Company's comprehensive loss and share-based payment reserves.

Significant areas requiring the use of management's judgments include:

*The recognition of deferred income tax assets*

A deferred tax asset is recognized to the extent that it is probable that future taxable profits will be available against which the asset can be utilized. To the extent that the Company does not consider it probable that a deferred tax asset will be recovered, it provides a valuation allowance against that excess.

*Treatment of development costs*

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 *Intangible Assets* are met. Those criteria require that the product is technically and economically feasible, which management assessed based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as of August 31, 2021 and February 28, 2021.

*Recoverability of the carrying value of intangible assets*

Evaluating the recoverability requires judgments in determining whether future economic benefits from sale or otherwise are likely. Evaluation may be more complex where activities have not reached a stage that permits a reasonable assessment of the viability of the asset. Management must make certain estimates and assumptions about future events or circumstances including, but not limited to, the interpretation of marketing and sales data, as well as the Company's financial ability to continue marketing and sales activities and operations.

*Going concern*

These consolidated financial statements have been prepared in a going concern basis, which assumes that the Company will continue operating for the foreseeable future and be able to realize its assets and discharge its liabilities and commitments in the normal course of business. Management has assessed the Company's ability to raise financing and concluded that going concern basis of accounting is appropriate.

## RISK RELATING TO OUR BUSINESS

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***COVID-19 Pandemic, natural disasters, public health crises, political crises, climate change and other catastrophic events or other events outside of our control may damage the facilities or disrupt the operations of our strategic partners, outside-party manufacturers, suppliers or other outside parties upon which we rely, and could delay or impair our ability to initiate or complete or commercialize our products.***

Our strategic partners, outside-party manufacturers, suppliers and other outside parties upon which we rely have operations around the world and are exposed to a number of global and regional risks outside of our control. These include, but are not limited to natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods or monsoons; public health crises, such as pandemics and epidemics; political crises, such as terrorism, war, political instability or other conflict; or other events outside of our control.

We cannot predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the outside parties with whom we engage, including the suppliers, regulators and other outside parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The duration and impact of the COVID-19 outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. If the COVID-19 outbreak continues or increases in severity and results in expanded or prolonged travel, commercial or other similar restrictions, we could experience supply, logistics or other disruptions, which could have a negative impact on our ability to conduct research and development. The pandemic also makes it more difficult to market and sell our technology, as many conferences have been canceled, and generally, it is more difficult to have face-to-face meetings, which is critical for sales. The COVID-19 outbreak may impact our ability to raise additional capital and/or impact our ability to continue our clinical trials.

*Our ability to continue as a going concern is dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis.*

We have expended and continue to expend substantial funds in connection with our commercialization of the MiQLab System and product development activities. In addition, we expect to incur significant expenses and add personnel necessary to operate as a public company. We expect that our operating losses may fluctuate significantly from quarter to quarter and year to year due to product development activities and the timing of sales, if any, of the MiQLab Systems.

Funds generated from our operations may be insufficient. Accordingly, we may need to raise substantial additional capital to continue to fund our operations, support sales and marketing programs, support research and development programs, planned clinical testing, regulatory approvals, manufacturing capabilities, and the purchase of inventory to meet potential, expected demand. LexaGene anticipates raising additional funds for these purposes through equity financings, debt financing, collaborations with other companies, and/or from other sources. There can be no assurance that additional funding or partnerships may be available on terms acceptable to the Company. The current financing environment in the United States and Canada, particularly for diagnostic companies like us, is exceptionally challenging and we can provide no assurances as to when such an environment may improve. Further, the uncertainty with respect to our operations and the market generally due to the COVID-19 pandemic may also make it challenging to raise additional capital on favorable terms, if at all. For these reasons, among others, we cannot be certain that additional financing may be available on acceptable terms for the Company. If financing is available, it may be on terms that adversely affect the interests of our existing shareholders.

### *Operating history*

LexaGene is still commercializing its products and establishing its business and therefore may be subject to the risks associated with early-stage companies, including uncertainty of the success and acceptance of its products, uncertainty of revenues, markets and profitability and the continuing need to raise additional capital. The Company's business prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in this stage of development. Such risks include the evolving and unpredictable nature of the Company's business, the Company's ability to anticipate and adapt to a rapidly evolving market, acceptance by consumers of the Company's products, the ability to identify, attract and retain qualified personnel and the ability to generate sufficient revenue or raise sufficient capital to carry out its business plans. There can be no assurance that the Company may be successful in adequately mitigating these risks.

### Competition

The diagnostics market in which the Company participates is highly complex and competitive. The Company may compete with other companies that are developing or have developed genetic analyzers designed to exploit similar markets to those in which we intend to penetrate. Many of these other companies have substantially greater resources. There can be no assurance that developments by other companies may not adversely affect the competitiveness of the Company's technologies. The diagnostic industry is also characterized by extensive research efforts and rapid technological change. Competition can be expected to increase as technological advances are made and commercial applications for diagnostic technologies increase. Competitors of the Company may use different technologies or approaches to develop products similar to the products which the Company has developed, or may develop new or enhanced products or processes that may be more effective and less expensive. There can be no assurance that any product developed by the Company may compete successfully or that research and new industry developments may not render the Company's products obsolete or uneconomical.

### Technical risks

Although LexaGene has successfully installed several MiQLabs for commercial sale, the Company continues to make small changes to the technology to improve reliability and performance. New hardware configurations are being tested and fluidic scripts continue to be optimized. As expected with any new technology, continual improvements are required to make the technology competitive.

False Positive Risk (poor specificity): LexaGene's technology relies on effectively cleaning re-useable components after each sample is processed. If this cleaning is not effective, there is a high risk of carry-over contamination (i.e., false positives for subsequently processed samples). The Company is in the process of setting thresholds used to determine if a sample is positive or negative for the targeted genetic sequence. Carry-over contamination influences the values of these thresholds, which affects both the specificity and sensitivity of the system for detecting the targeted sequences (e.g., pathogens). If the cleaning is unreliable or insufficient, the industry may reject the technology due to poor sensitivity and poor specificity. Furthermore, the MiQLab assembles a series of real-time PCR reactions in a flow cell. During the creation and assembly of these reactions, it is possible to have reaction-to-reaction carry-over, where the leading reaction leaves behind reagents that are picked up by the following reaction. In the event the leading reaction is positive for a particular pathogen, it is possible that the following reaction would be a false positive for a test that has reagents in the same fluorescent channel as the positive signal in the leading reaction. These two issues could result in poor specificity for LexaGene's technology. It is possible LexaGene's technology may generate too many false positive results to be competitive in the market.

False Negative Risk (poor sensitivity): Pathogens, particular RNA-based pathogens such as SARS-CoV-2 and influenza, naturally mutate to create variants. If mutations arise in areas of the genome that LexaGene's tests target, then there is a possibility for a false negative result. Furthermore, should LexaGene's technology assemble the reaction inappropriately, or experience chemical inhibition due to a chemical in the loaded sample or due to mis-directed fluidic movements, then it is possible to generate a false negative result. Lastly, some sample matrices may not be handled well by LexaGene's automated sample preparation, resulting in inhibitors to RT-PCR being introduced into the reactions. These inhibitors could prevent the successful detection of target molecules. These three issues could result in poor sensitivity for LexaGene's technology. It is possible LexaGene's technology may generate too many false negative results to be competitive in the market.

Sample Processing Risk: Each matrix processed by the instrument is different. It is unclear how well, if at all, the instrument may be able to process some matrices, possibly eliminating some target markets. Currently, limited work has been done on processing milk, blood, and other fat-containing liquids, particulate laden samples, or viscous samples, so the uncertainty surrounding these matrices is high. Management expects specialized cartridges and chemistries may be needed to effectively process these more challenging matrices. It is also possible that customers frequently processing some matrices may require their instrument to be serviced more frequently due to clogged or broken parts. It is completely unknown

how robust or fragile this technology may be when used in the field for extended periods of time. Potentially, significant harm may occur to the microfluidics that would require costly repairs. It is also unknown how expensive it may be to make repairs to the MiQLab instruments. It is possible LexaGene's technology may not be robust enough to handle different matrices and thus would harm our ability to be competitive in the market.

Dormancy Risk: LexaGene's microfluidic technology relies on priming fluids up to a valve head. It is also unknown how well this may will handle periods of dormancy when the instrument is not being used over longer periods of time. If fluids pull away from the valve head during periods of dormancy, there may be the risk that the following sample would fail to be processed successfully. It is possible LexaGene's technology may not function reliably after periods of dormancy and this would harm our ability to be competitive in the market.

Time-to-Result Risk: If LexaGene cannot get its time-to-result and time-to-process the next sample down to competitive times, this would adversely impact sales. Some vendors of molecular tests for SARS-CoV-2 can generate results in as little as 30 minutes. They often achieve such short time to result by skipping sample preparation and assembling a single reaction. In contrast, LexaGene's technology is designed to do a quality sample preparation and looks for numerous pathogens, which adds to the time to result. Furthermore, at the conclusion of processing a sample, the MiQLab initiates an automated cleaning protocol, which further adds to the time until the next sample can be processed. Like with all diagnostic technology, there is a relationship between data quality and time to result. The faster different processes are pushed, the higher the likelihood of having less accurate results or sensitivity. LexaGene can push its technology faster to achieve a time-to-result of approximately one hour, but is currently choosing to go slower in the interest of higher sensitivity and quality data. We expect our time to result to change depending on the market we are targeting, each of which value false negatives and false positives slightly differently, and also different sample matrices require different sample preparation protocols, and RNA targets require a reverse transcription step. Each of these elements adds to the time to result, so it is not appropriate to think of all of LexaGene's tests taking ~ one hour, as some may take significantly more time. Furthermore, as LexaGene better optimizes its system, we expect to lower the time-to-result from where it currently is today. This may also include introducing software checks that allow a positive result to be reported as soon as it is deemed statistically significant. If LexaGene cannot get its time to result and it's time to next sample down to competitive times, this would harm LexaGene's chances of success.

Size of our Systems: Some molecular tests are now being offered that effectively fit in the palm of your hand. These tests generally look for one target (e.g., SARS-CoV-2). LexaGene's technology was designed for quality sample preparation and syndromic testing. Our technology is considerably larger than handheld instruments. Many of our target customers may view our technology to be too large and too heavy. There is the possibility our customers may not adopt our technology due to its size, if there were to happen, it would be detrimental to the success of the company.

Throughput Risk: Some of the Company's potential customers in industries such as food safety may require a significant number of samples to be run per day, exceeding the capacity of a single MiQLab or even multiple MiQLabs. These customers would prefer a higher-throughput system capable of processing more than 100 samples per day. As such, these customers would be unlikely to purchase LexaGene's technology until the Company develops and markets as higher-throughput system to better meet their needs.

Robustness Risk: It is possible some of the components inside the MiQLab may fail during usage. If LexaGene cannot manufacturer a system that works reliably, then the cost of repair and the frustration experienced by our customers could harm the Company's chances of long-term success.

Accuracy Risk: LexaGene is competing against technologies that provide more complete information than possible with a limited real-time PCR multiplex reaction performed by the MiQLab. For example, culture followed by mass spectroscopy is capable of identifying a 100 or more species of bacteria. The same is true for microarrays and sequencing. Because of the limited microbial testing capability of the MiQLab, it is certain that some infections may be missed. The lack of MiQLab assays for some pathogens may adversely

affect the Company. Likewise, typical sensitivity testing involves incubating growing cells in the presence of antibiotics for a phenotypic read-out. Genetic testing does not provide the same level of accuracy in regard to how resistant a bacterium is to a particular drug, since the resistance to some antibiotics is caused by multiple genes, and is influenced by single nucleotide polymorphisms, and transcription and translation modifiers. In short, translating a genetic result into a true phenotypic response is very difficult and sometimes impossible for some antibiotics. LexaGene's antimicrobial resistance panel focuses on detecting genes (e.g., beta lactamases) that are responsible for conferring resistance to beta lactam drugs, such as penicillins, cephalosporins, carbapenems, and beta-lactamase inhibitors. Also, tests have been developed for vancomycin and lincosamides resistance. Nonetheless, it is expected that our tests for antimicrobial resistance may never be 100% accurate. This may result in some false negative results that potentially may have a negative consequence on the tested animal/person and likewise on the Company and its products.

### Regulatory

LexaGene anticipates selling its technology into highly regulated industries. As such, the Company may be subject to the authority and approvals of certain regulatory agencies, including Health Canada, the FDA, the CFDA, CE Mark and applicable health authorities in other countries, with regard to the development, testing, manufacture, marketing and sale of its products. The process of obtaining such approvals can be costly and time consuming, and there can be no assurance that regulatory approvals may be obtained or maintained. Any failure to obtain (or significant delay in obtaining) or maintain Health Canada, FDA, Notified Body or CFDA approvals (or, to a lesser extent, approval of applicable health authorities in other countries) for LexaGene's new or existing products could materially adversely affect LexaGene's ability to market its products successfully and could therefore have a material adverse effect on the business of LexaGene.

LexaGene may be unable to complete the development of its product on the expected timeline, or at all. In addition, if regulatory authorities require additional time or studies to assess the performance, reliability, and safety of our product(s), LexaGene may not have or be able to obtain adequate funding to complete the necessary steps for approval for the product or may be unable to technically meet their requirements. Additional delays may result if the USDA, FDA or other regulatory authority/certifications (e.g., Association of Official Analytical Chemists International (AOAC International)) recommend non-approval or restrictions on any potential approval. Studies required to demonstrate the performance, reliability, and safety of LexaGene's products are time consuming and expensive to complete. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of product development and may vary among jurisdictions. To date, LexaGene has not obtained regulatory approval for any product and it is possible that none of its existing products under development now or in the future may ever obtain regulatory approval. Delays in regulatory approvals or rejections of applications for regulatory approval in Canada, the United States, Europe, Japan or other markets may result from a number of factors, many of which are outside of LexaGene's control. The lengthy and unpredictable approval process, as well as the unpredictability of future clinical trials and other studies, may result in LexaGene's failure to obtain regulatory approval to market any of its products, which would significantly harm LexaGene's business.

Diagnostic products are regulated as class II medical devices by the FDA and comparable international agencies and require either clearance or authorization to market and sell for clinical use (*in-vitro* diagnostics market (IVD)). The traditional FDA regulatory path prior to clinical marketing is to obtain 510(k) pre-market notification process or pre-market approval (PMA), depending on the application. In a public health emergency, the FDA often allows for 'Emergency Use Authorization' (EUA), which allows vendors to sell their technology for a specified purpose in clinical diagnostics. The requirements for EUA are substantially less than what is required for 510(k) or PMA, and accordingly are often considerably faster and less expensive to obtain. All companies that are granted EUA for a particular application are expected to work towards and eventually obtain 510(k) clearance, as they are not deemed to be equivalent in the eyes of the FDA. The FDA is currently accepting EUA applications for COVID-19 testing. There is the possibility the FDA may close the window of opportunity to applying for EUA for COVID-19 testing and LexaGene may be forced to go through the traditional 510(k) clearance path, which could take year(s) to obtain – if it is

obtained at all. Obtaining the requisite regulatory approvals can be expensive and may involve considerable delay. If the Company fails to obtain, or experiences significant delays in obtaining, regulatory approvals for the diagnostic products we develop, we may not be able to launch or successfully commercialize such products in a timely manner, or at all. Furthermore, part of the FDA studies include work with outside parties who must use LexaGene's technology in either a reference laboratory or point-of-care settings. Given these parties are currently overwhelmed with testing samples for the current pandemic, these parties may not have the capacity to take on an EUA study with LexaGene. If LexaGene is unable to find parties willing to assist in the required FDA studies, it is possible LexaGene may be unable to complete the required studies for EUA submission.

LexaGene's technology is considered "open-access". It is possible the FDA may not support the use of this feature, as end-users have control over making changes. If so, it is possible the FDA may not authorize the use of the LexaGene's open-access feature for human clinical diagnostics. Also, it is possible the end users may find it too difficult to operate and generate consistent results, which could be detrimental to the Company. Furthermore, LexaGene's MiQLab uses both guanidine-based buffers for lysis and hypochlorite-based buffers for decontamination. These solutions are kept separate on the system, but nonetheless, the FDA is cautious about workflows using both chemicals, as improper mixing may create poisonous cyanide gas. To date, the FDA has not received reports of illness due to these potentially hazardous interactions.<sup>21</sup>

### *Commercial platform development*

LexaGene is supporting the manufacturing of a commercial platform. The cost of establishing and maintaining that infrastructure may exceed the cost effectiveness of doing so. In order to market any products, LexaGene must expand its sales, marketing, manufacturing, managerial and other non-technical capabilities or arrange with outside parties to perform these services. If LexaGene does not have adequate sales, marketing and distribution capabilities, whether independently or with outside parties, LexaGene may not be able to generate sufficient product revenue to become profitable. LexaGene competes with many companies that have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of an outside party to perform sales and marketing functions, LexaGene may be unable to compete successfully against these more established companies. Furthermore, LexaGene's relationships with its outside-party suppliers are subject to various risks and uncertainties that are outside of its control; including agreements with outside party suppliers not being renewed or being terminated in accordance with their terms.

### *Operating results may fluctuate*

LexaGene's operating results may fluctuate in the future, which may cause the Company's trading price for the shares to decline. LexaGene's net sales, expenses and operating results may vary significantly from year to year and quarter to quarter for several reasons, including, without limitation:

- the ability of LexaGene's sales force to effectively market and promote the Company's products, and the extent to which those products gain market acceptance;
- the possibility that cybersecurity breaches, data breaches, and other disruptions could compromise the LexaGene's information or result in the unauthorized disclosure of confidential information;
- the rate and size of expenditures incurred on LexaGene's, manufacturing, sales, marketing, and product development efforts;
- the availability of key components, materials and contract services, which depends on the LexaGene's ability to forecast sales, among other things;
- variations in timing and quantity of product orders;
- temporary manufacturing interruptions or disruptions;

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<sup>21</sup> <https://www.mlo-online.com/diagnostics/specimen-collection/article/21141072/fda-says-exposure-to-cyanide-gas-possible-with-some-workflows-to-test-for-covid19>

- the timing and success of new product and new market introductions;
- increased competition, or new technologies;
- product recalls;
- litigation, including product liability, patent, employment, securities class action, stockholder derivative, general commercial and other lawsuits;
- volatility in the global market and worldwide economic conditions;
- the financial health of the LexaGene's customers and their ability to purchase LexaGene's products in the current economic environment;
- an epidemic or pandemic, such as the current COVID-19 pandemic.

As a result of any of these factors, LexaGene's consolidated results of operations may fluctuate significantly, which may in turn cause the trading price of the notes and the shares to fluctuate.

***Increased cybersecurity requirements, vulnerabilities, threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, products, solutions, services and data.***

Increased global cybersecurity vulnerabilities, threats, computer viruses and more sophisticated and targeted cyber-related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of the Company and its customers, business partners' and suppliers' products, systems and networks and the confidentiality, availability and integrity of data on these products, systems and networks. As the perpetrators of such attacks become more capable, and as critical infrastructure is increasingly becoming digitized, the risks in this area continue to grow. While we attempt to mitigate these risks by employing a number of measures, including employee training, monitoring and testing, and maintenance of protective systems and contingency plans, we remain potentially vulnerable to additional known or unknown threats, and we cannot assure that the impact from such threats may not be material. In addition to existing risks, the adoption of new technologies may also increase our exposure to cybersecurity breaches and failures. Additionally, we have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer-imposed controls. Despite our implementation of controls to protect our systems and sensitive, confidential or personal data or information, we may be vulnerable to material security breaches, theft, misplaced, lost or corrupted data, employee errors and/or malfeasance (including misappropriation by departing employees) that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions. In addition, a cyber-related attack could result in other negative consequences, including damage to our reputation or competitiveness, remediation or increased protection costs, litigation or regulatory action. Although we have experienced occasional actual or attempted breaches of our computer systems, to date we do not believe any of these breaches has had a material effect on our business, operations or reputation.

***Establishing product distribution***

LexaGene must attract, train and retain a domestic sales force or align with an outside product distribution company. This may take longer than expected, be ineffective, cost more than we anticipate, or be limited by COVID-19 restrictions among other issues.

***Quarterly revenue, gross margins and operating results may fluctuate***

LexaGene's revenues can change from one quarter to the next and gross margins are subject to a number of factors that could cause lower than expected or even negative gross margins, some items that may influence LexaGene's quarterly revenue, gross margins and operating results may include:

- lower than anticipated demand for the MiQLab System;
- pricing campaigns designed to attract customers;

- timing of collection of sales proceeds;
- consumable giveaways;
- manufacturing issues;
- fluctuations in material costs;
- repair and warranty costs; and
- pressure to reduce prices from competition.

LexaGene may be unable to compete within its markets successfully, and there could be a material adverse effect on the Company's business results of operations and financial condition.

### *Manufacturing*

The manufacture of our products is highly complex and requires precise high-quality manufacturing that may be difficult for us to achieve, particularly in regards to achieving system-to-system uniformity/reliability. The Company may experience difficulties in the manufacturing and qualification of our products in a timely and cost-effective basis. Problems with supply chain and manufacturing could lead to insufficient quantities for sales. This is particularly true given many part vendors and contract manufacturers are either shut down or operating at reduced capacities due to the COVID-19 pandemic. These difficulties may cause delays associated with ramping up the production of our products and may increase delivery lead-times and increase the costs of manufacturing our products. Future production of our products may require the development of new manufacturing technologies and expertise, which we may be unable to develop. Our failure, including the failure of our contract manufacturers, to achieve and maintain the required high manufacturing standards could result in delays or failures in product testing or delivery to end-users, cost overruns, product recalls or sales withdrawals, increased warranty costs or other problems that could harm our business and prospects.

### *Cost of manufacturing our products and consumables*

The diagnostic markets are extremely price-competitive. If our cost to manufacture products are not competitive with others or if volume manufacturing and cost reductions associated with volume manufacturing are not attained, it may adversely impact our ability to penetrate the market or be profitable. Our ability to penetrate the diagnostic markets may depend in part on the cost of manufacturing and if we do not successfully distinguish our product from others, our entry into the market and our ability to secure customer contracts may be adversely affected. Manufacturing our initial systems and consumables is happening at very low volumes, which is extremely expensive and results in negative profit margins for early sales. Investors may falsely interpret these early numbers and get discouraged and sell their stock, thereby preventing the opportunity for the Company to grow, achieve higher volume manufacturing, and realize better profit margins that are required for a healthy company.

We intend to continue to dedicate a significant portion of our resources to the commercialization of our MiQLab System and its related test menu. As a result, to the extent that our cost to manufacture our consumables are too high or not commercially successful or are withdrawn from the market for any reason, our operating results, financial condition and critical MiQLab development programs would be harmed.

In addition, we have limited manufacturing, marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on the costs of our manufacturing of our products and consumables, attracting customers for our products and building brand loyalty. If the costs of our products and consumables are too expensive, we may not generate the demand we expect and our revenues and our ability to achieve profitability may be significantly impaired.

### *Interruption of raw material supply and manufacturing operations*

LexaGene's manufacturing operations are dependent upon third-party suppliers, making its vulnerable to supply shortages and price fluctuations, which could harm its business.

Many of the components and materials that comprise LexaGene's products are currently manufactured by a limited number of suppliers. A supply interruption or an increase in demand beyond LexaGene's current suppliers' capabilities could harm LexaGene's ability to manufacture our products until a new source of supply is identified and qualified. LexaGene's reliance on these suppliers subjects the Company to a number of risks that could harm its business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in components;
- lack of long-term supply arrangements for key components with LexaGene's suppliers;
- inability to obtain adequate supply in a timely manner, or on reasonable terms;
- inability to redesign one or more components in the MiQLab systems in the event that a supplier discontinues manufacturing such components and LexaGene's inability to source it from other suppliers on reasonable terms that may cause the inventory obsolescence;
- difficulty locating and qualifying alternative suppliers for MiQLab System's components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delay in supplier deliveries.

Any interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers, which would have an adverse effect on the LexaGene's business.

#### *Process risk*

LexaGene's consolidated financial statements are prepared within a framework of IFRS selected by management and approved by the company's audit committee. The assets, liabilities, and expenses reported in the consolidated financial statements depend on varying degrees of estimates made by management. An estimate is considered a critical accounting estimate if it requires management to make assumptions about matters that are highly uncertain and if different estimates could have been used that would have a material impact. The significant areas requiring the use of management estimates relate to provisions made for impairment of non-financial assets, amortization of property and equipment and intangible assets, the recognition and valuation of tax liabilities and tax assets, provisions and the assumptions used in determining share-based compensation. These estimates are based on historical experience and reflect certain assumptions about the future that we believe to be both reasonable and conservative. Actual results could differ from those estimates. LexaGene continually evaluates these estimates and assumptions.

#### *Loss of key personnel*

LexaGene depends on the business and technical expertise of its management and it is unlikely that this dependence may decrease in the near term. Loss of the Company's key personnel could slow the Company's ability to innovate and execute on company and product development goals, although the effect on ongoing operations would be manageable as experienced key operations personnel could be put in place. As the Company's operations expand, additional general management resources may be required. If LexaGene expands its operations, the ability of the Company to recruit, train, integrate and manage a large number of new employees is uncertain and failure to do so would have a negative impact on the Company's business plans.

*We may not be able to attract, train and retain a sufficient number of qualified employees to maintain and grow our business*

We expect that our potential expansion into areas and activities requiring additional expertise, such as governmental approvals, manufacturing, sales, marketing and distribution may place additional requirements on our management, operational and financial resources. We expect these demands may require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. There is currently aggressive competition for employees who have experience in technology, biology and engineering. The failure to attract and retain such personnel or to develop such expertise could materially adversely affect our business, financial condition and results of operations.

If the COVID-19 outbreak continues or increases in severity and results in expanded or prolonged travel, social distancing, quarantines, the closure of our office or other similar restrictions, we could experience difficulties in recruiting, hiring, training and retaining employees, which could have a negative impact on our ability to conduct research and development or commercialize products.

*Product price risk*

The manufacturing costs for our instrument and the associated consumables continues to fluctuate. Accordingly, the final selling price of LexaGene's instrument and tests may fluctuate, along with performance, may affect user adoption. If these prices are not favorable for LexaGene, there is a possibility that the Company may not generate significant sales. Furthermore, LexaGene's product is limited in the number of samples that can be run in a day. The Company is depending on customers running a sufficient number of samples per day to bring in the required revenue to ultimately support the operations of the Company. If this revenue, specifically the profit margin, is too low, the Company may not be able to maintain operations.

*Additional financing requirements and access to capital*

LexaGene may require substantial, additional funds to support future sales and marketing programs, research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities, and the purchase of inventory to meet potential, expected demand. LexaGene anticipates raising additional funds for these purposes through equity financings, debt financing, collaborations with other companies, and/or from other sources. There can be no assurance that additional funding or partnerships may be available on terms acceptable to the Company. Additionally, there are many conditions beyond the Company's control that have a direct impact on the level of investor interest in the purchase of Company securities. For example, the Canadian and United States Stock markets have been volatile and may continue to fluctuate significantly in response to a number of factors the Company cannot control.

*Protection of intellectual property*

LexaGene's success depends in part on its ability to maintain or obtain and enforce patent and other intellectual property protections for its processes and technologies and to operate without infringing upon the proprietary rights of outside parties or having outside parties circumvent the rights the Company owns or licenses. The Company has applications and registrations in the United States and other jurisdictions, and expects to seek additional patents and registrations in the future.

Patents provide some degree of protection for intellectual property; however, patent protection involves complex legal and factual determinations and is therefore uncertain. LexaGene cannot be assured that its patents or patent applications may be valid or may issue over prior art. Additionally, LexaGene cannot be assured that the scope of any claims granted in any patent may be commercially useful or may provide adequate protection for the technology used currently or in the future. LexaGene cannot be certain that the creators of its technology were the first inventors of inventions and processes covered by its patents and patent applications or that they were the first to file. Accordingly, it cannot be assured that its patents may

be valid or may afford protection against competitors with similar technology or processes. Despite the Company's efforts to protect its proprietary rights, unauthorized parties may attempt to copy or otherwise obtain and use its proprietary information. Monitoring unauthorized use of confidential information is difficult and the Company cannot be certain the steps taken to prevent unauthorized use of confidential information may be effective. In addition, the laws governing patent protection continue to evolve and are different from one country to the next, all of which causes further uncertainty in the usefulness of a patent. In addition, issued patents or patents licensed to LexaGene may be successfully challenged, invalidated, circumvented or may be unenforceable so that the Company's patent rights would not create an effective competitive barrier.

Moreover, the laws of some countries may not protect LexaGene's proprietary rights to the same extent as do the laws of the United States. There are also countries in which LexaGene intends to sell its products, but has no patents or pending patent applications, or trademark registrations. LexaGene's ability to prevent others from making or selling duplicate or similar technologies may be impaired in those countries in which there is no intellectual property protection. If LexaGene is not able to adequately protect its intellectual property and proprietary technology, its competitive position, future business prospects and financial performance may be adversely affected. Unpatented trade secrets, technological innovation and confidential know-how are also important to LexaGene's success. Although protection is sought for proprietary information through confidentiality agreements and other appropriate means, these measures may not effectively prevent disclosure of proprietary information; and it cannot be assured that others may not independently develop the same or similar information or gain access to the same or similar information. In view of these factors, LexaGene's intellectual property positions have a degree of uncertainty. Setbacks in these areas could negatively affect LexaGene's ability to compete and materially and adversely affect its business, financial condition and results of operations.

#### *Infringement of intellectual property rights of others*

We may infringe the intellectual property rights of others. LexaGene's commercial success depends, in part, upon it not infringing or violating intellectual property rights owned by others. The markets in which the Company intends to compete has participants that own, or claim to own, intellectual property. The Company cannot determine with certainty whether any existing outside-party patents, or the issuance of any new outside-party patents, would require it to alter its technologies or products, obtain licenses or cease certain activities.

The Company may in the future receive claims from outside parties asserting infringement and other related claims. Litigation may be necessary to determine the scope, enforceability and validity of outside - party intellectual property rights or to protect, maintain and enforce the Company's intellectual property rights. Some of LexaGene's competitors have, or are affiliated with companies having, substantially greater resources, and these competitors may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods than the Company can. Regardless of whether claims that it is infringing or violating patents or other intellectual property rights have any merit, those claims could:

- adversely affect the Company's relationships with future distributors and dealers of its products;
- adversely affect its reputation with potential customers;
- be time-consuming and expensive to evaluate and defend;
- cause product shipment delays or stoppages;
- divert management's attention and resources;
- subject the Company to significant liabilities and damages;
- require it to enter into royalty or licensing agreements; or
- require it to cease certain activities, including the sale of products.

If it is determined that the Company has infringed, violated or is infringing or violating a patent or the intellectual property right of any other person or if it is found liable in respect of any other related claim, then, in addition to being liable for potentially substantial damages, the Company may be prohibited from

developing, using, distributing, selling or commercializing certain technologies and products unless it obtains a license from the holder of the patent or other intellectual property right. The Company cannot assure that it may be able to obtain any such license on a timely basis or on commercially favorable terms, or that any such licenses may be available, or that workarounds may be feasible and cost-efficient. If it does not obtain such a license or find a cost-efficient workaround, the Company's business, operating results and financial condition could be materially affected and it could be required to cease related business operations in some markets and restructure its business to focus on its continuing operations in other markets.

### *Large accumulated deficit*

LexaGene has a large accumulated deficit, expects future losses, and may never achieve or maintain profitability. It has incurred substantial losses since inception and expects to incur additional operating losses in the future as a result of research and development costs and ongoing operating costs including the additional costs of operating as a public company. The extent of LexaGene's future losses is highly uncertain, and its prospects must be considered in light of the risks and uncertainties encountered by a company in the early stage of product development in the continuously evolving diagnostics market, including the risks described throughout this document. If LexaGene cannot successfully address these risks, its business and financial condition may suffer.

### *Conflicts of interest*

Some of the Company's directors are or may become directors of other biotech companies and as such may have a conflict of interest requiring them to abstain from certain decisions. Conflicts, if any, may be subject to the procedures and remedies of the British Columbia Business Corporations Act ("**BCBCA**").

### *Novel business model*

Until now, pathogen testing has been mostly completed by outside parties that require the shipment of samples. Often, this process takes days to return results. LexaGene proposes to provide end users with an alternative to the shipment method, by offering them a technology to perform testing on site. Technology that allows for on-site testing already exists by other vendors and new technologies are rapidly being developed by established and startup companies, making it difficult to predict how well LexaGene's technology may be accepted. Accordingly, adoption may require marketing and education and it may take time for its products to gain acceptance.

LexaGene's technology is considered "open-access". The Company views 'Open-access' markets as markets in which the end-users have the ability to use LexaGene's technology to automate customized genetic screens. This unique feature is expected to drive some adoption in pharmaceutical companies, academic institutions, water processing plants, and in other industries. However, it is possible the Company may not be able to implement this feature in a fashion that is acceptable to end users, who might find it too difficult to operate and generate consistent results, which would be very detrimental to the Company. If LexaGene cannot successfully address these risks, its business and financial condition may suffer.

### *Early stage commercialisation*

LexaGene has generated little revenues. The Company expects to spend significant amounts of capital on sales and marketing programs, as well as continued research and development for its technology. There is no assurance the Company's products can be produced at reasonable costs or be successfully marketed and sold. In the future, the Company expects its operating expenses may increase and it may need to generate significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it may be profitable.

### *Continuing development and sale of products*

The pathogen testing market has experienced rapid technological development with new product frequently being introduced. Accordingly, the Company's future success depends upon its ability to enhance its current products and to develop, introduce and sell the most accurate products at competitive prices. The development of new technologies and products involves time, substantial costs and risks. The Company's ability to successfully develop new technologies depends in large measure on its ability to maintain a technically skilled research and development staff and to adapt to technological changes and advancements in the industry. The success of new product introductions depends on a number of factors including timely and successful product development, market acceptance, the effective management of purchase commitments, the availability of components in appropriate quantities, and the Company's ability to manage distribution and production issues related to new product introductions. If the Company is unable, for any reason, to enhance, develop, introduce and sell new products in a timely manner, or at all, in response to changing market conditions or customer requirements or otherwise, its business may be harmed.

### *Failure to manage growth*

The Company's failure to manage its growth successfully may adversely impact its operating results. The Company's ability to manage growth may require it to continue to build its operational, financial and management controls, contracting relationships, marketing and business development plans and controls and reporting systems and procedures. The Company's ability to manage its growth may also depend upon a number of factors, including the ability for it to rapidly:

- expand its internal financial controls significantly so that it can maintain control over operations;
- attract and retain qualified technical personnel in order to continue to develop reliable and flexible products to meet evolving customer needs;
- build a sales team to keep customers and channel partners informed regarding the technical features and key selling points of its products and services;
- develop support capacity for customers as sales increase; and
- build a channel network to create an expanding presence in the evolving marketplace for its products and services.

An inability to achieve any of these objectives could harm the business, financial condition and results of operations of the Company.

### *No long-term customer commitments*

Potential customers of the Company may request placement orders for particular needs. If the Company performs well on a particular placement, then the customer may place new orders with the Company for additional pathogen testing instruments and supplies. The Company may have no commitment from a customer beyond the ordered placement. As a result, the Company's success may be dependent upon its ability to outperform competitors and win repeat business from existing customers, while continually expanding the number of customers for whom it provides services. Because the Company may not have long-term contracts for its future products, management may not accurately predict future revenue streams and there may be no assurance that customers would continue to use the Company's platform, or that the Company would be able to replace departing potential customers with new potential customers that provide the Company with comparable revenue.

### *Foreign exchange*

As the Company grows and does business in foreign markets, including the United States, it is quite possible that transactions may take place in foreign currencies. At this point, the Company does not participate in any hedging activities. Although it cannot predict the effect of possible foreign exchange gains

or losses in the future, if gains or losses occurred, then they could have a material adverse effect on the Company's business, results of operation, and financial condition. Since the Company only sells its products accepting the United States Dollar as payment, sales in Canada or other foreign countries, should they occur, fluctuations in exchange rates could affect the pricing of its products and negatively influence customer demand.

### *Taxes*

Tax examinations are often complex as tax authorities may disagree with the treatment of items reported by the Company, the result of which could have a material adverse effect on its financial condition and results of operations.

### *Insurance and uninsured risks*

The Company's business may be subject to a number of risks and hazards generally, including general liability. Such occurrences could result in damage to property, inventory, facilities, personal injury or death to end-customers or operators, damage to the properties of the Company, or the properties of others, monetary losses and possible legal liability. Although the Company maintains insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance may not cover all the potential risks associated with its operations. The Company may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. The Company might also become subject to liability which may not be insured against or which the Company may elect not to insure against because of premium costs or other reasons. Losses from these events may cause the Company to incur significant costs that could have a material adverse effect upon its financial performance and results of operations.

### *Potential product liability risks*

The use of existing products or those under development by the Company may entail risk of product or other liability. The obligation to pay any product liability claim could have a material adverse effect on the business, financial condition and future prospects of the Company.

Product liability insurance is expensive. Companies are subject to the risk of potential product liability claims. Should such claims be successful, plaintiffs could be awarded significant amounts of damages. The Company may try to obtain the insurance coverage for its products and potential liability exposure that it considers adequate, but there is no guarantee that the Company may be able to obtain, maintain in effect or increase its insurance on acceptable terms or at reasonable costs, or that such insurance may provide the Company with adequate protection against potential liability. The Company may have to use distributors for the sale of some of the products of which it is the owner, and such distributors may not have general insurance or liability insurance pertaining to the use of the products sold by them or may have insurance that does not cover such liability in an amount sufficient to adequately protect the Company.

If the Company's products are defectively designed, manufactured or labeled, contain defective components or are misused, the Company may become subject to substantial and costly litigation by the Company's customers. In addition, if its operating guidelines are found to be inadequate, the Company may be subject to liability. These claims could divert management's attention from its core business, be expensive to defend and result in sizable damage awards against the Company. The Company may not have sufficient insurance coverage for all future claims. The Company may not be able to obtain insurance in amounts or scope sufficient to provide the Company with adequate coverage against all potential liabilities.

### *Holding company status*

The Company is a holding company and essentially all of its operating assets are the capital stock of its subsidiaries. As a result, investors in the Company are subject to the risks attributable to its subsidiaries.

As a holding company, the Company conducts substantially all of its business through its subsidiaries, which are expected to generate the majority of its revenues. Consequently, the Company's cash flows and ability to complete current or desirable future enhancement opportunities are dependent on the future earnings of its subsidiaries and the distribution of those earnings to the Company. The ability of these entities to pay dividends and other distributions may depend on their operating results and may be subject to applicable laws and regulations which require that solvency and capital standards be maintained by such companies and contractual restrictions contained in the instruments governing their debt. In the event of a bankruptcy, liquidation or reorganization of any of the Company's subsidiaries, holders of indebtedness and trade creditors may generally be entitled to payment of their claims from the assets of those subsidiaries before any assets are made available for distribution to the Company.

***The market price of the Common Shares is volatile and may not accurately reflect the long-term value of the Company***

Securities markets have a high level of price and volume volatility, and the market price of securities of many companies have experienced substantial volatility in the past, often based on factors unrelated to the financial performance or prospects of the companies involved. These factors included macroeconomic developments in North America and globally, and market perceptions of the attractiveness of particular industries. The price of the Units is also likely to be significantly affected by changes in the financial condition or results of operations as reflected in its financial reports. If an active market for the Common Shares does not continue, the liquidity of an investor's investment may be limited and the price of the Common Shares may decline below the price at which such Common Shares were purchased. If an active market does not continue, investors may lose their entire investment in the Common Shares. As a result of any of these factors, the market price of the Common Shares at any given point in time may not accurately reflect the long-term value of the Company.

Due to volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

There are many message boards, chat rooms, blogs, or written articles that are followed by shareholders. Opinions regarding LexaGene are expressed on these message boards that may or may not be factual in nature. The Company is not in a position to respond to or actively influence these news feeds. Influencers can drastically affect the stock price based on little to no material information, and potentially could cause a collapse in the stock price that may not be recoverable by the Company.

***Dilution***

LexaGene may issue additional securities, which may dilute a shareholder's holdings in the Company. LexaGene's articles permit the issuance of an unlimited number of Common Shares. The directors of the Company have discretion to determine the price and the terms of further issuances. Moreover, additional Common Shares may be issued by the Company in the form of restricted share units or incentive stock options under the Company's omnibus incentive plan and upon the exercise of outstanding options and warrants. The market price of the Common Shares could decline because of issuances by the Company or sales by existing shareholders of Common Shares in the market, or the perception that these sales could occur. Sales by shareholders might also make it more difficult for the Company to sell equity securities at a time and price deemed appropriate.

***A positive return in an investment in the Common Shares is not guaranteed***

There is no guarantee that an investment in the Company's Common Shares may earn any positive return in the short term or long term. A purchase of the Company's Common Shares involves a high degree of risk and should be undertaken only by investors whose financial resources are sufficient to enable them to assume such risks and who have no need for immediate liquidity in their investment. An investment in the

Common Shares is appropriate only for investors who have the capacity to absorb a loss of some or all of their investment.

### *Global economy*

An economic downturn of global capital markets has been shown to make the raising of capital by equity or debt financing more difficult. The Company may be dependent upon the capital markets to raise additional financing in the future, while it establishes a user base for its products. As such, the Company is subject to liquidity risks in meeting its development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favorable to the Company and its management. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, this could have an adverse impact on the Company's operations and the trading price of the Company's shares.

Should the Company decide to start selling its products on international markets, tariffs imposed by other countries on US products might hinder the Company's sales in those markets.

### *Political and economic instability*

The Company may be affected by possible political or economic instability. The risks include, but are not limited to, elections, domestic or foreign terrorism, military operations, war, extreme fluctuations in currency exchange rates and high rates of inflation. Operations may be affected in varying degrees by government regulations. The effect of these factors cannot be accurately predicted.

### *Legal matters*

In the normal course of operations, LexaGene may be subject to a variety of legal proceedings, including commercial, product liability, employment as well as governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, and cause us to incur significant expenses. Furthermore, because litigation is inherently unpredictable, and can be very expensive, the results of any such actions may have a material adverse effect on our business, operations, or financial condition.

The Company is not aware of any contingencies or pending legal proceedings at October 26, 2021.

## **OUTSTANDING EQUITY INSTRUMENTS**

As of October 26, 2021, we had authorized an unlimited number of common shares. The Company's equity capitalization table is as follows:

	<b>October 26, 2021</b>	<b>August 31, 2021</b>	<b>February 28, 2021</b>
Common Shares	119,285,610	119,120,597	118,566,834
Warrants	16,142,741	16,142,741	19,324,991
Stock Options <sup>(1)</sup>	5,670,950	5,543,600	3,722,000
Restricted Share units	2,587,928	2,640,941	2,368,254
<b>Total</b>	<b>143,687,229</b>	<b>143,447,879</b>	<b>143,982,079</b>

**Notes:**

<sup>(1)</sup> 2,537,200 of the 5,670,950 stock options are vested and exercisable at October 26, 2021.

The Company has 16,142,741 warrants outstanding at October 26, 2021, which are exercisable into common shares at exercise prices ranging between CAD\$0.52 and CAD\$1.10.

The Company has 5,670,950 stock options outstanding at October 26, 2021, which are exercisable into common shares at exercise prices ranging between CAD\$0.49 and CAD\$1.15.

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## SUBSEQUENT EVENTS

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Subsequent to August 31, 2021, the Company issued 165,013 shares upon vesting of RSUs.

On October 13, 2021, the Company granted 150,000 RSUs. The RSUs vest as follows: 10% on March 13, 2022, 15% on each of July 13, 2022, December 13, 2022, May 13, 2023, October 13, 2023, December 13, 2023, and February 13, 2024. RSUs expire on February 13, 2024.

The Company also granted 150,000 incentive stock options to employees on October 13, 2021. Stock options are exercisable at \$0.57 per common share and vest at 10% 6 months after the grant date and 15% every 6 months thereafter. Stock options expire on October 13, 2026.

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## ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED BY THE COMPANY

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In January 2020, the IASB issued amendments to IAS 1, which clarify the criteria used to determine whether liabilities are classified as current or non-current. These amendments clarify that current or non-current classification is based on whether an entity has a right at the end of the reporting period to defer settlement of the liability for at least twelve months after the reporting period. The amendments also clarify that 'settlement' includes the transfer of cash, goods, services, or equity instruments unless the obligation to transfer equity instruments arises from a conversion feature classified as an equity instrument separately from the liability component of a compound financial instrument. The amendments were originally effective for annual reporting periods beginning on or after January 1, 2022. However, in May 2020, the effective date was deferred to an annual reporting periods beginning on or after January 1, 2023.

In May 2021, the IASB issued targeted amendments to IAS 12, *Income Taxes*. The amendments aim to reduce diversity in reporting through clarifying that companies are required to recognize deferred taxes on transactions where both assets and liabilities are recognized. These transactions generally include right-of-use assets and lease liabilities and decommissioning and similar liabilities. The amendments are effective for annual periods beginning on or after January 1, 2023, and earlier application is permitted.

The Company is currently assessing the impact of these amended standards but does not expect them to have a material impact on the financial statements.

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## DISCLAIMER

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The information provided in this document is not intended to be a comprehensive review of all matters concerning the Company. It should be read in conjunction with all other disclosure documents provided by the Company, which can be accessed at [www.sedar.com](http://www.sedar.com). No securities commission or regulatory authority has reviewed the accuracy or adequacy of the information presented herein.

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## CAUTIONARY STATEMENT ON FORWARD LOOKING INFORMATION

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Certain statements contained in this document constitute "forward-looking statements". Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance, or achievements of the Company to be materially different from any previously predicted results or performance expressly stated or implied by such forward-looking statements. Such factors include, among others, the following: product development technical risks, life sciences market risks, fluctuation in the equity markets that affect the Company's ability to raise capital, government regulations, competition, litigation risks, and commercial viability risks.