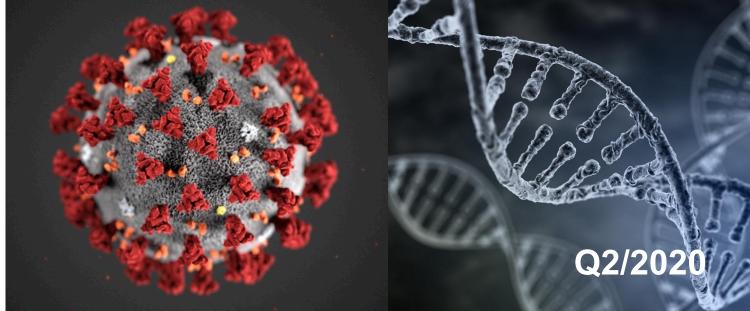
# LexaGene

TSX.V: LXG | OTCQB: LXXGF

# AUTOMATED PATHOGEN DETECTION

**Investor Presentation** 





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TSX.V: LXG | OTCQB: LXXGF

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# **Corporate Overview**



- LexaGene is a molecular diagnostics company developing genetic analyzers for pathogen detection
- Bringing reference laboratory quality data
   to the point of need with ~ 1-hour test results
- In addition to pursuing other markets, LexaGene is applying for
   FDA Emergency Use Authorization to deploy COVID-19 testing

# The need for better COVID-19 Testing



Singleplex tests likely return a negative result. Practitioners left guessing: False negative? Flu?

- Many different viral infections present with similar symptoms to COVID-19
- Value in multiplexed diagnostics higher confidence in results (more positive results)

More than 2.2M cases and 100,000 deaths in the US.

# **Limitation of Tests on the Market**



#### Isothermal Genetic Amplification:

- Results in 5 30 minutes
- Looks for one pathogen at a time
- Lacks sample preparation, hurting sensitivity

#### Rapid Antigen Detection:

- Results in >15 minutes
- Poor sensitivity

#### Quantitative Real-time RT-PCR:

- Gold standard
- Highly sensitive and specific
- Provides quantitative information on viral burden

#### **Point-of-Care**

\\*

TESTS ARE NOT ALL CREATED EQUAL

# Laboratory

#### **NEED:**

Sensitivity + speed + multiplex ✓

**LexaGene** → **POC** 





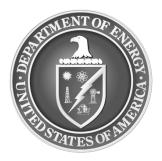
# LexaGene's Microfluidic Technology



# **Technology History**



- Inventor of the technology: Dr. Jack Regan, LexaGene CEO
- Was the lead author developing LX2 predecessor technology at LLNL for biodefense and public safety
- US Government spent >\$20M on predecessor instruments
- Includes instrument adopted by BioWatch Program









LexaGene has secured an exclusive license to market its microfluidic technology from Lawrence Livermore National Laboratory

# Technology Highlights / Markets





Sample In - Answers Out in ~1 hour (vs. 1 – 3 days)



**98.2% concordance** with reference lab data



Low cost per test



Razorblade business model, high margin



Targeting **markets** valued at over \$40 Billion USD



2 **Patents** issued,5 pending



**Human Clinical Diagnostics (COVID-19 Testing)** ~ \$12.9B



**Veterinary Diagnostics** ~ \$5.4B



Food Safety ~ \$24.4B



Open-Access Use > \$10B





# **LX Genetic Analyzer**



Unlike any other sample-to-answer system on the market.



#### **Open-access**

Run customized testing or our validated assays. Open-access feature can be rapidly configured to detect new pathogens (like COVID-19).



#### Low cost per test

- Cartridge
- Reagents



#### Ease-of-use

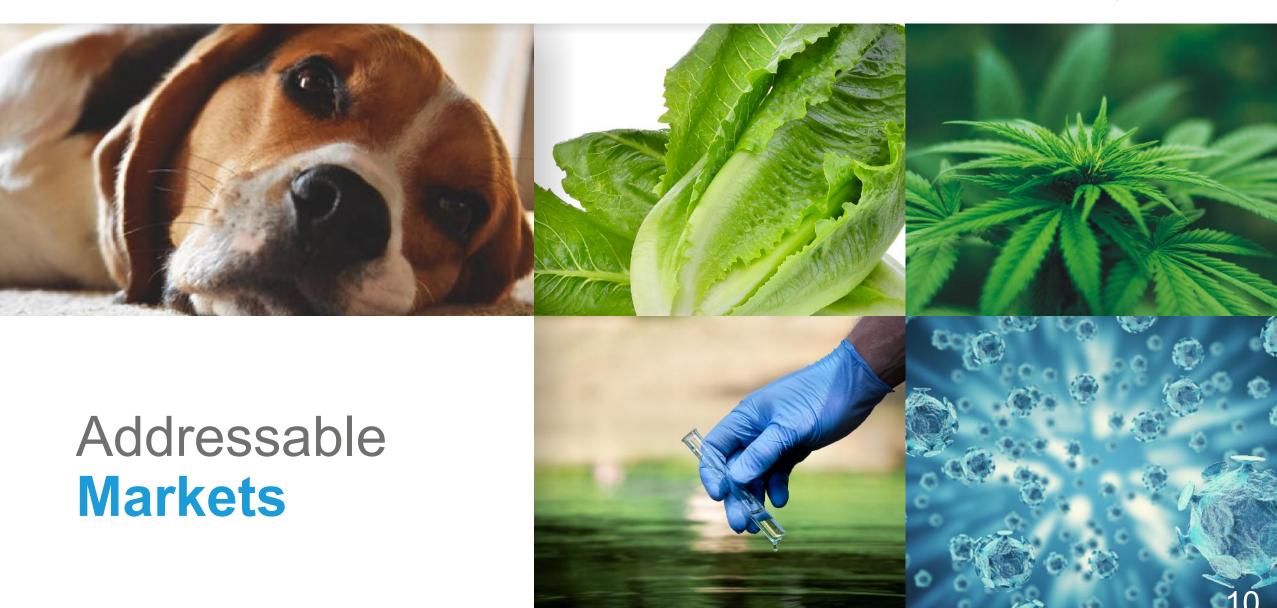
Simply load the sample and a cartridge onto the instrument and press 'Go'. No pipetting required.



#### Benefits of multiplex genetic testing

- Gold-standard sensitivity/specificity
- Tests for 27 targets at once
- Avoid false positive & negative results
- Results in ~ 1-hour





# Top Markets Targeted





# Clinical Diagnostics (\$12.9B USD by 2025)<sup>1</sup>

- COVID-19 testing
- 18K Reference labs in US<sup>2</sup>
- Prevent future outbreaks



# Veterinary Diagnostics (\$5.4B USD by 2024)<sup>3</sup>

- Better decision making
- Improve use of antibiotics
- Reduce wait times



#### Food Safety (\$24.4B USD by 2025)<sup>4</sup>

- Avoid costly recalls, brand damage
- Ship fresher and safer food
- FDA changes mandated testing



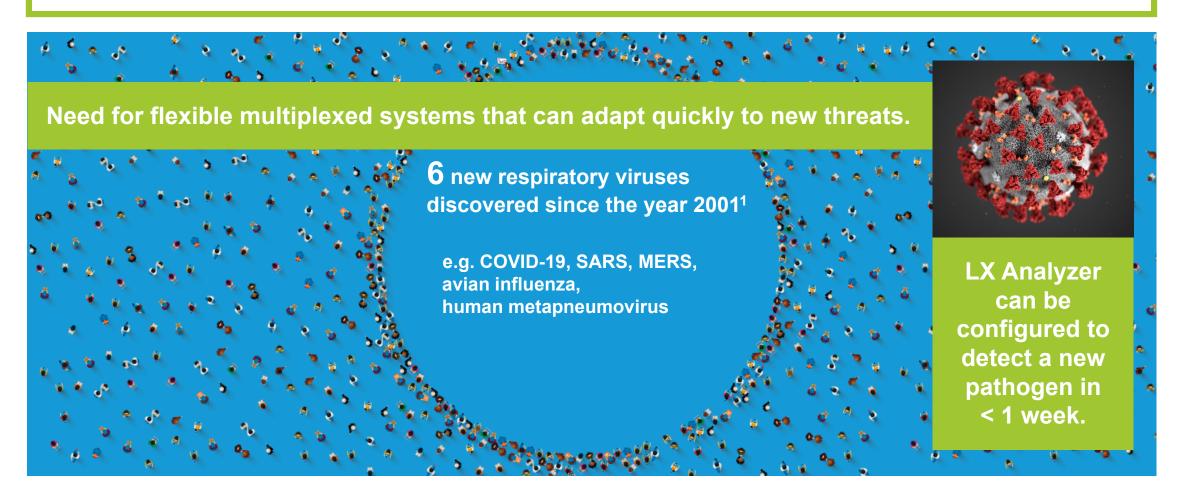
#### **Open-Access Markets (customized testing)**

- Pharma, academic labs, biodefense, etc.
- Water Safety Testing
- Genotyping Market
- Agricultural pathogen testing

# **Market Drivers – Pandemic Prevention**



Rapid, early detection is the key to preventing the <u>next</u> pandemic.



# **Market Drivers - Veterinary Diagnostics**



Point-of-care testing gives vets the ability to **diagnose in ~ 1-hour** rather than waiting 1 - 3 days for results.



- 25,000 pet hospitals in the US¹
- 90 million dogs and 95 million cats in the US<sup>2,3</sup>
- 5.4 million urine sediment tests run per year in the US<sup>4</sup>

# **Market Drivers - Food Safety**



48 million illnesses due to contaminated food EVERY YEAR in the US<sup>1</sup>

# 1.1 B tests are performed each year<sup>2</sup>

- Multiple tests run per sample (salmonella, E.coli, listeria, etc.)
- More testing (new requirements Food Safety Modernization Act)

Typical food recall costs ~\$30 million<sup>3</sup>



# **Open Access Market**









2,772 Biotech Companies<sup>1</sup> (Roche Headquarters)

9,509 Life Sciences Companies<sup>1</sup> 173 Universities (>10M in NIH grants)<sup>2</sup> (Illumina Research Park)

(Harvard Medical School)











Supporting
Data &
Comparative
Studies



# LX Analyzer Prototype Studies



#### **Human and Veterinary Diagnostics**

#### **Beta Testing** results:

- >98% concordant with reference lab data
- Tested urine and other sample types
- Improved in-clinic sample processing
- Detected
  - multiple pathogens at once
  - antibiotic resistance factors





#### COVID-19 Study

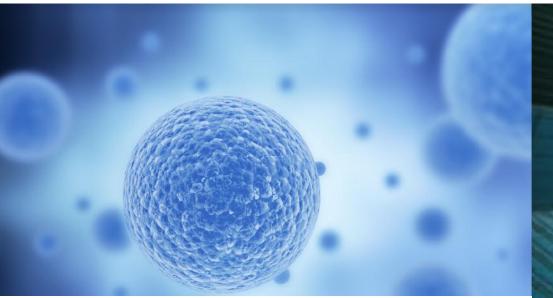
 Pre-Commercial Testing in US Hospital for COVID-19 testing at Dartmouth-Hitchcock Medical Center

#### LexaGene Studies

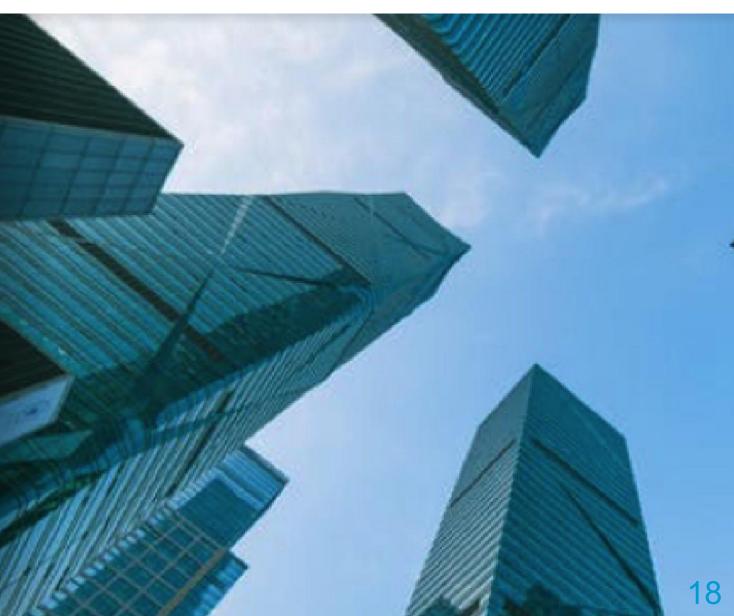
In-lab LX Analyzer results:

- 100% concordance on superbug testing
- Detected
  - multiple UTI pathogens at once
  - live and dead E. coli on lettuce
  - agricultural fungus that causes billions in crop loss
  - gene mutations from cheek swabs





# Financial Section



# **Corporate Highlights**





**LexaGene** - Public since October of 2016 | Headquartered near Boston, Massachusetts

Current Employees 26

Shares
Outstanding
93,213,651

Warrants
Outstanding
20,682,172

Capital
6 financings
totaling \$18.6M USD

Stock Options and RSUs Outstanding 7,495,963 (2,813,250 vested)

Exchange TSX V: LXG OTCQB: LXXGF

# **Recurring Revenue Stream**

From Consumables

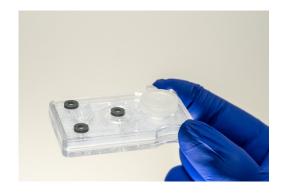


# **Disposable Sample Preparation Cartridge**

- Razor blade business model
- High gross margin per sample tested

## **Reagent Panels**

- Each panel allows for each sample to be screened for 27 targets plus controls
- Open-access feature allows for customized testing



Single-use cartridge
used every time a
sample is processed to
purify genetic material
from the sample

LX Analyzer draws from a **Reagent panel** using microfluidics to perform tests.



# **Current Activities**



- Applying for FDA Emergency Use Authorization for COVID-19 testing
- Establishing Quality Manufacturing System (ISO 13485)
- Beginning manufacturing commercial units
- Making key sales hires
- Start selling first commercial LX Analyzers and tests

## Team



LexaGene has assembled a management team and board with over 192 years of combined experience in developing equipment and research in medical technology and life-science companies

The team brings extensive experience in genetics, microfluidics, food and water safety, infectious disease and diagnostics

The team has authored **75 patents**, launched 50+ FDA-cleared products and been involved in substantial M&A activity



Dr. Jack Regan Founder, CEO



Daryl Rebeck **President, Co-founder** 



Tom Slezak Director



Dr. Manohar Furtado **Director** 



Joseph Caruso Director



Jeff Mitchell **CFO** 



Greg Dale **VP Product Dev + Manufacturing** 



Jay Adelaar **VP of Capital Markets** 



Dr. Nathan Walsh **VP of Applications** + Bioinformatics



Steve Armstrong **Senior Director Operations** 



















# **Summary**



LexaGene's disruptive technology meets critical testing needs.





Fast turnaround time (~1 hour)



Anyone can operate - load in seconds



Great sensitivity and specificity, multiplex



Open-access (customizable)



Low cost per sample tested

First-of-its-kind, open-access on-site pathogen detection system

# **Appendix: References**



#### Slide 11:

- <sup>1</sup> Clinical: https://www.globenewswire.com/news-release/2019/07/16/1883243/0/en/Infectious-Disease-Diagnostics-Market-Worth-12-88-Billion-by-2025-Exclusive-Report-by-Meticulous-Research.html
- <sup>2</sup> Clia Labs: M. Schwartz. Clinical Chemistry, 45:5 p739 –745 (1999)
- <sup>3</sup> Veterinary Diagnostics: https://www.marketwatch.com/press-release/over-8-cagr-animal-diagnostics-market-will-reach-54-billion-by-2024-2018-09-24
- <sup>4</sup> Food safety: https://www.bccresearch.com/market-research/food-and-beverage/food-safety-testing-technologies-markets-report.html

#### Slide 12:

<sup>1</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4379558/

#### Slide 13:

- <sup>1</sup> https://news.vin.com/vinnews.aspx?articleId=32051
- <sup>2</sup> https://www.statista.com/statistics/198100/dogs-in-the-united-states-since-2000/
- <sup>3</sup> https://www.statista.com/statistics/198102/cats-in-the-united-states-since-2000/
- <sup>4</sup> https://research-doc.credit-

suisse.com/docView?language=ENG&format=PDF&document\_id=1057479581&source\_id=em&serialid=AVM6IPJ1QCdC%2FbWeS%2BV%2FqLDMRB9gq2ruoiYKQ6IdYx4%3D

#### Slide 14:

- <sup>1</sup> https://www.cdc.gov/foodsafety/foodborne-germs.html
- <sup>2</sup> https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/a-look-at-the-microbiology-testing-market/
- <sup>3</sup> Grocery Manufacturers Association

#### Slide 15:

- <sup>1</sup> https://www.labiotech.eu/tops/countries-recruit-biotech-talents-2017/
- <sup>2</sup> https://report.nih.gov/award/index.cfm?ot=DH,27,47,4,52,64,41,MS,20,16,6,13,10,49,53,86,OTHDH&fy=2018&state=&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=

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