



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

July 25, 2022

Jack Regan
Chief Executive Officer
LexaGene Holdings Inc.
500 Cummings Center
Suite 4550
Beverly, Massachusetts 01915

Re: LexaGene Holdings Inc.
Form 10-12G
Filed June 28, 2022
File No. 000-56456

Dear Dr. Regan:

We have reviewed your filing and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response and any amendment you may file in response to these comments, we may have additional comments.

Registration Statement on Form 10-12G filed June 28, 2022

Glossary of Key Terms and Definitions, page v

1. Please clarify the meaning of scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain the meaning of validated reagents, high-value pathogens, lysis, syndromic, chromogenic, isothermal, fluorogenic, beta lactam drugs, beta-lactamase inhibitors, and guanidine-based and hypochlorite-based buffers.

Item 1. Description of Business, page 1

2. We note your disclosure on page 2 and elsewhere that you commercialized your MiQLab System between late 2019 and 2020 and began selling units. We also refer to your disclosure on page F-24 that you commercialized the MiQLab System as of February 28,

2022 and that both the alpha and beta prototype phases were completed in prior years.

Please reconcile your disclosures and also clarify throughout your registration statement (including, but not limited to, page 20) that you have commercialized your MiQLab System for veterinary diagnostics and biologics contract manufacturing to date, have not obtained regulatory approval for any of your products and that your plans to begin clinical studies for human diagnostics and enter the food testing market remain uncertain. We refer to your disclosure on pages 9 and 18.

3. We note your disclosure starting on page 4 relating to your collaborative agreement with Texas A&M Veterinary Medical Diagnostics Laboratory, the engagement of Launchworks to manufacture components used in the MiQLab System, your partnership with Ethos Discovery and the cooperative R&D agreement with the U.S. Army's DEVCOM. Please expand your disclosure to include the material terms of such agreements, collaborations and partnerships. If such collaborations and agreements are material to your business, please file such agreements as exhibits to the registration statement as required by Item 601(b)(10) of Regulation S-K or tell us why it is not material and balance your disclosure accordingly.
4. You disclose on page 29 that you rely on certain single-source suppliers for many of your products, components and materials. Please expand your disclosure, where appropriate, to identify the suppliers on which you rely and the material terms of your agreements with such parties. Refer to Item 101(h)(4)(v) of Regulation S-K.
5. We note your disclosure on page 28 that your manufacturing costs continue to fluctuate for your MiQLab System and the associated consumables. You also disclose on page 29 that your manufacturing operations are dependent on a limited number of suppliers that make you vulnerable to supply shortages, supply chain issues and price fluctuations. Please expand your disclosure of any known trends in supply chain and manufacturing disruptions and delays. Discuss whether you have undertaken any mitigation efforts, and if so, whether such efforts have introduced new material risks relating to product quality or reliability. Additionally, expand your risk factor section to describe the product outages, the causes and the impact on your operations.

Brands and Trademarks, page 12

6. We refer to your disclosure relating to your registered trademarks in Canada and the United States. Please clarify, if true, that the registered trademarks relate to your patent portfolio, and expand your disclosure to include the type of patent protection granted and expiration date of each patent. Please also explain the meaning of your references to different "Class" categories.
7. We note your disclosure on page 5 that you filed three patent applications with the U.S. Patent and Trademark Office ("USPTO") on July 17, 2019 relating to the technology of the unique sample preparation extraction method, data and image processing algorithms and a microfluidic element of the instrument. You also disclose on page 6 the filing of a

provisional patent application with the USPTO relating to the expanded testing capabilities of your LX Analyzer technology on April 16, 2020. Please revise your disclosure here to discuss such patent applications, including the types of patent protection and expected expiration date for each patent application.

Product Overview, page 13

8. We refer to your disclosure on page 13 that your MiQLab System has two unique features, specifically its open-access nature and ability to process large sample volumes, which are “not available in any other commercial product for automated bio-detection” and make your product a “first of its kind.” You also disclose on page 33 that both features of your MiQLab System are currently not authorized by the FDA and may be blocked for human clinical diagnostics. Please balance your disclosure in this section to clarify that such features have not been authorized by the FDA for human diagnostics.

Targeted Markets, page 14

9. With respect to the biologics contract manufacturing market, please revise to expand your disclosure relating to your competitors and any regulatory requirements you may be subject to.

Regulatory Matters, page 21

10. We note your disclosure on page 21 that you sold your MiQLab Systems to veterinary hospitals and laboratories in reliance on certain exemptions from CVS licensing requirements. Please expand your disclosure of the CVS licensing requirements and the exemptions you relied on to sell your products in the veterinary diagnostics market.

Research and Intellectual Property, page 21

11. We refer to your disclosure on page F-17 relating to the license agreement you entered into with Lawrence Livermore National Security (“LLNS”) on February 4, 2015. Please include disclosure of your license agreement here and revise to disclose when the last-to-expire licensed patent is scheduled to expire, the aggregate amounts paid to date (including any upfront or executive fees) and the termination provision.

Risk Factors, page 22

12. We note the disclosure of your emerging growth company status on the cover page. Please expand your disclosure here to include material risk factors relating to your status as an emerging growth company.

13. We note your disclosure on page 39 that the market for penny stocks has suffered in recent years from fraud and abuse. Please revise to clarify that your common shares may be considered a “penny stock” and thereby subject to additional sale and trading regulations that may make it more difficult to sell.

Item 4. Security Ownership of Certain Beneficial Owners and Management, page 47

14. Please include a footnote to your table to identify the natural persons who are the beneficial owners of the shares held by the entities affiliated with Meridian LGH Holdings LLC.

Item 5. Directors and Executive Officers, page 48

15. We note several of your executive and director biographies where the principal occupation and employment is unclear during the past five years. Please discuss the principal occupation and employment for the past five years, including the name and principal business of any corporation or other organization. Please also indicate any other directorships held during the last five years for each director and disclose the potential risks relating to any current directorships, namely potential conflicts of interest and the effects they may have on shareholders both here and in the Risk Factors section. See Item 401(e) of Regulation S-K.

Item 10. Recent Sales of Unregistered Securities, page 67

16. Please refer to Item 701 of Regulation S-K and provide all required disclosures in this section. For example, please disclose the names of the principal underwriters, if any, and for any securities not publicly offered, please name the persons or identify the class of persons to whom the securities were sold.

Exhibits

17. We note that certain portions of Exhibits 3.2 and 10.5 have been redacted. Pursuant to Item 601(b)(10)(iv), please revise your exhibit index to reflect that certain information has been excluded from these exhibits.

General

18. Pursuant to Section 12(g)(1) of the Exchange Act, the Form 10 becomes effective automatically 60 days after the initial filing date. At that time, you will be subject to the reporting requirements of the Exchange Act. In addition, we will continue to review your filing until all of our comments have been addressed. If the review process has not been completed before the effectiveness date you should consider withdrawing the Form 10 registration statement to prevent it from becoming effective and, as applicable, file a new Form 10 registration at such time as you are able to respond to any remaining issues or comments.

Jack Regan
LexaGene Holdings Inc.
July 25, 2022
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We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact Tracie Mariner at 202-551-3744 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Herbert Ono, Esq.