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September 30, 2022

Office of Life Sciences Division of Corporation Finance U.S. Securities & Exchange Commission 100 F Street, NE Washington, D.C. 20549

Attn: Dillon Hagius Jason Drory Li Xiao Daniel Gordon

Re: Legend Biotech Corporation Form 20-F for Fiscal Year Ended December 31, 2021 Filed March 31, 2022 File No. 001-39307

Ladies and Gentlemen:

On behalf of our client Legend Biotech Corporation (the "**Company**"), an exempted company incorporated under the laws of the Cayman Islands, we submit to the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") this letter setting forth the Company's responses to the comments contained in the Staff's letter dated September 2, 2022 on the Company's Form 20-F for its fiscal year ended December 31, 2021 filed on March 31, 2022 (the "**Form 20-F**").

The Company intends to implement the responses and disclosures noted below below by amending the Form 20-F in the future (the "Amended Form 20-F"). Each of the Staff's comments are repeated below in bold, followed by the Company's response to the comments.

Form 20-F for Fiscal Year Ended December 31, 2021

Certain Information, page 1

1. We note that your definition of "China" or "PRC" specifically excludes Hong Kong and Macau. Please revise the definition of "China" or the "PRC" to include Hong Kong and Macau and clarify that the only time that "PRC or China" does not include Hong Kong or Macau is when you reference specific laws and regulations adopted by the PRC. Additionally, clarify that the "legal and operational" risks associated with operating in China also apply to operations in Hong Kong and Macau. Lastly, discuss any commensurate laws and regulations in Hong Kong and Macau, where applicable throughout your filing, and the risks and consequences to you associated with those laws and regulations.

Response to Comment 1:

In response to the Staff's comment, the Company will revise the disclosure on page 1 of the Amended Form 20-F as follows:

Via EDGAR



"CERTAIN INFORMATION

In this Annual Report on Form 20-F, unless otherwise indicated or the context otherwise requires, "Legend Biotech" refers to Legend Biotech Corporation, a Cayman Islands holding company, "PRC subsidiaries" refer to Legend Biotech's subsidiaries incorporated in the PRC (as defined below) and "we," "us," "our," and the "Company" refer to Legend Biotech and its consolidated subsidiaries. References to "GenScript" or "Genscript" refer to Genscript Biotech Corporation, our majority stockholder.

This Annual Report on Form 20-F contains translations of Renminbi amounts into U.S. dollars at specified rates solely for the convenience of the reader. We make no representation that the Renminbi or U.S. dollar amounts referred to in this Annual Report on Form 20-F could have been or could be converted into U.S. dollars or Renminbi, as the case may be, at any particular rate or at all. Unless otherwise noted, translations of Renminbi amounts into U.S. dollars in this Annual Report are made based on an exchange rate of RMB 6.38 to \$1.00, which is the exchange rate as of December 31, 2021 as published by The People's Bank of China.

Various amounts and percentages set out in this document have been rounded and, accordingly, may account for apparent discrepancies in the tables appearing herein. Unless otherwise indicated or the context otherwise requires, references in this Annual Report to:

- "ADSs" are to the American depositary shares, each of which represents two of our ordinary shares;
- "ADRs" are to the American depositary receipts that evidence the ADSs;
- "China" or "PRC" refers to the People's Republic of China, and solely in the context of describing PRC rules, laws, regulations and other legal and tax matters, excludes rules, laws, regulations and other legal and tax matters of the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan; "Greater China" does not exclude the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan;
- "ordinary shares" are to ordinary shares of our company, par value \$0.0001 per share;
- "Renminbi" or "RMB" refers to the legal currency of the PRC;
- "Series A Preference Shares" are to the Series A preference shares, par value \$0.0001 per share; and
- "US\$," "U.S. dollars," "\$," or "dollars" are to the legal currency of the United States.

For our organization structure as of the date of this annual report, see "Item 4. Information on the Company—C. Organizational Structure."

The Company will also discuss any commensurate laws and regulations in Hong Kong and Macau, where applicable throughout its filing, and the risks and consequences to the Company associated with those laws and regulations.



D. Risk Factors

Risk Factors Summary, page 4

2. Please revise your summary of risk factors so that you disclose the risks that your corporate structure and being based in or having the majority of the company's operations in China poses to investors is prominent and upfront. In particular, describe the significant regulatory, liquidity, and enforcement risks. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your securities. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in Chinabased issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of your securities to significantly decline or be worthless.

Response to Comment 2:

In response to the Staff's comment, the Company will revise its list of Risks Related to Doing Business in China in its summary of risk factors in the Amended Form 20-F as follows:

"Risks Related to Doing Business in China

- Risks related to doing business in China, including the impact of extensive Chinese regulation on the pharmaceutical industry.
- The heightened level of government involvement in the Chinese economy and uncertainties regarding legal protections in the PRC legal system.
- PRC governmental authorities may intervene or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.
- The adverse effect of an ongoing investigation involving our majority shareholder and former CEO and chairman.
- PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiaries.
- The approval of, or filing or other procedures with, the CSRC or other governmental authority may be required in connection with issuing our equity securities outside of the PRC under Chinese law, and, if required, we cannot



predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.

- The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for three consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022, or two consecutive years if the AHFCAA is enacted. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections. PRC governmental control of currency conversion may limit our ability to utilize our revenues effectively and affect the value of our ADSs.
- PRC regulations relating to its offshore investment activities by PRC residents and enterprises may increase our administrative burden and restrict our sino-foreign and cross-border investment activity.
- Monetary, economic, political, environmental, social, and trade disputes between the U.S. and China.
- The heightened level of actions by the U.S. Department of Commerce targeting Chinese companies."

In addition, the Company respectfully wishes to clarify for the Staff that, while the Company has operations in China, the majority of the Company's operations are not in China. Rather, the majority of the Company's operations are in the United States. Specifically, the Company is headquartered in New Jersey, United States of America. For the year ended December 31, 2021, less than 20% of the Company's operating expenses were generated in China, and the Company expects that percentage to continue to decrease in future years. During the year ended December 31, 2021, less than \$4 million of the Company's revenue was generated in China, and the Company does not expect significant revenue to be generated by its China operations in the future.

<u>Part I</u>

Item 3. Key Information, page 4

3. At the onset of Part I, please disclose prominently that you are not a Chinese operating company but a Cayman Islands holding company with operations conducted by your subsidiaries. In addition, please provide early in the Business section a diagram of the company's corporate structure.

Response to Comment 3:

In response to the Staff's comment, the Company will include the following disclosure at the onset of Part I in the Amended Form 20-F:



"Legend Biotech is a Cayman Islands holding company and not a Chinese operating company. We operate through our operating subsidiaries located primarily in the United States, PRC and European Union. Our operations in the PRC, in addition to our business presence elsewhere in the world, are enabled by our subsidiaries based therein. Investors in our ADSs do not hold equity securities of our operating subsidiaries but hold equity securities of a Cayman Islands holding company. See "Item 4—Information On The Company—C. Organizational Structure Chart" for an illustration of our corporate structure."

Further, the Company will include early in "Item 4—Information on the Company" a diagram of the Company's corporate structure in the Amended Form 20-F.

4. Provide prominent disclosure about the legal and operational risks associated with being based in or having the majority of the company's operations in China. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of your securities or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to data security or anti-monopoly concerns, have or may impact the company's ability to conduct its business, accept foreign investments, or list on a U.S. or other foreign exchange.

Response to Comment 4:

In response to the Staff's comment, unless there are changes in relevant law or regulations, or in interpretations thereof that would necessitate changes to the below, the Company will add the following disclosure at the onset of Part 1 of the Amended 20-F:

"Our Holding Company Structure and China Operations

Legend Biotech is a Cayman Islands holding company and not a Chinese operating company. We operate through our operating subsidiaries located primarily in the United States, PRC and European Union. Our operations in the PRC, in addition to our business presence elsewhere in the world, are enabled by our subsidiaries based therein. Investors in our ADSs do not hold equity securities of our operating subsidiaries but hold equity securities of a Cayman Islands holding company. See "Item 4—Information On The Company—C. Organizational Structure Chart" for an illustration of our corporate structure.

We face various legal and operational risks and uncertainties associated with having a portion of our operations in China and the complex and evolving PRC laws and regulations. For example, we face risks associated with regulatory approvals or filing requirements on offerings conducted outside of the PRC and investment by individuals or entities outside of the PRC ("non-PRC investors") in issuers with operations in China, anti-monopoly regulatory actions and oversight on cybersecurity, data privacy and genetic information, if we fail to comply with relevant regulatory requirements, which may negatively impact our ability to conduct certain businesses, access investments by non-PRC investors or list on stock exchanges outside of the PRC. If we fail to comply with these regulatory requirements on our offerings and investments outside the PRC, the PRC could take actions against our PRC subsidiaries, which could materially and adversely affect our operations in the PRC. As a result, these risks could result in a material adverse change in our operations and the

value of our ADSs, significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline.

Our operations in China are governed by PRC laws and regulations. The PRC governmental authorities have significant oversight and discretion over the conduct of our business in China, and it may intervene in or influence our operations at any time where we are not or might not be compliant with PRC laws or regulations, which could result in a material adverse change in our operation and/or the value of our ADSs. Also, the PRC governmental authorities have recently indicated an intent to exert more oversight and control over offerings that are conducted outside of the PRC and/or investment by non-PRC investors in issuers with operations in China. Any such action could result in actions taken against our PRC subsidiaries, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. In addition, the implementation of industry-wide regulations directly targeting our operations could cause the value of our securities to significantly decline. Therefore, our shareholders and our business face potential uncertainty from actions taken by the PRC governmental authorities affecting our business in the PRC.

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to a significant degree of interpretation by PRC regulatory agencies and courts. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of these decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. Therefore, it is possible that our existing operations may be found not to be in full compliance with relevant laws and regulations in the future. In addition, the PRC legal system is based in part on governmental policies and internal rules, some of which are not published on a timely basis or at all, and which may be a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Recently, the PRC government has indicated an intent to exert more oversight and control over offerings that are conducted outside of the PRC and/or investment by non-PRC investors in issuers with operations in China, and initiated a series of regulatory actions and made a number of public statements, including cracking down on illegal activities in the securities market, enhancing supervision over companies with operations in China to be listed outside of the PRC, adopting new measures to extend the scope of cybersecurity reviews, and expanding efforts in anti-monopoly enforcement. As a result, risks to our business arise from, among other things, PRC governmental authorities' significant oversight and discretion over the business and financing activities of our PRC subsidiaries, the complex and evolving PRC legal system, frequent changes in laws, regulations and government policies, uncertainties and inconsistencies regarding the interpretation and enforcement of laws and regulations, uncertainties, difficulties or delays in obtaining regulatory approvals or completing filing procedures for listing on a non-PRC stock exchange or conducting certain business activities and increasing oversight on cybersecurity and data privacy related to the PRC government's recently issued statements and instituted regulatory actions and could result in actions taken against our

PRC subsidiaries, which could materially and adversely affect our operations in the PRC, and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline. Uncertainties in the PRC legal system and the interpretation and enforcement of PRC laws and regulations could limit the legal protection available to you and us, significantly limit, delay or hinder our ability to offer or continue to offer the ADSs, result in a material adverse effect on our business operations, and damage our reputation, which might further cause the ADSs to significantly decline in value.

For a detailed description of the risks associated with our operations in China, see "-D. Risk Factors-Risks Related to Doing Business in China."

The Company will also revise the risk factor referenced below in the Amended 20-F as follows:

"The PRC legal system contains uncertainties, which could limit the legal protections available to you and to us.

In 1979, the PRC government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. Our PRC subsidiaries are subject to laws and regulations applicable to foreign-invested enterprises in China. In particular, they are subject to PRC laws, rules and regulations governing foreign companies' ownership and operation of pharmaceutical businesses. Such laws and regulations are subject to change, and their interpretation and enforcement involve uncertainties, which could limit the legal protections available to us and our investors. In addition, we cannot predict the effect of future developments in the PRC legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement of such laws, or the preemption of local regulations by PRC laws, rules and regulations.

Moreover, the PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to a significant degree of interpretation by PRC regulatory agencies and courts. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the non-precedential nature of these decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. Therefore, it is possible that our existing operations may be found not to be in full compliance with relevant laws and regulations in the future. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy



than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

In addition, the PRC government has recently announced its plans to enhance its regulatory oversight of PRC companies listing outside of the PRC. The Opinions on Strictly Cracking Down on Illegal Securities Activities issued on July 6, 2021 called for:

- tightening oversight of data security, cross-border data flow and administration of classified information, as well as amendments to relevant regulation to specify responsibilities of PRC companies listed outside of the PRC with respect to data security and information security;
- enhanced oversight of companies listed outside of the PRC as well as equity fundraising and listing by
 PRC companies outside of the PRC; and
- extraterritorial application of China's securities laws.

As the Opinions on Strictly Cracking Down on Illegal Securities Activities were recently issued, there are great uncertainties with respect to the interpretation and implementation thereof. The PRC government may promulgate relevant laws, rules and regulations that may impose additional and significant obligations and liabilities on Chinese companies listed outside of the PRC regarding data security, cross-border data flow, and compliance with China's securities laws. It is uncertain whether or how these new laws, rules and regulations and the interpretation and implementation thereof may affect us, but among other things, our ability to obtain external financing through the issuance of equity securities outside of the PRC could be negatively affected."

In addition, the Company respectfully wishes to clarify for the Staff that, as noted in the Company's response to Comment 2 and the Amended Form 20-F, while the Company has operations in China, the Company is not based in China and a majority of the Company's operations are in the United States. Further, the Company respectfully wishes to clarify for the Staff that, while the PRC government's actions could impact the Company's pre-clinical research and development activities in China, the Company's ability to use the investigator initiated trial model for early clinical development of products being developed in China, biologics application approvals in China and product commercialization in China, the Company's business operations with regard to the development, manufacturing and sales of its lead product candidate, ciltacabtagene autolucel ("cilta-cel"), in its primary markets would not be materially affected by any such PRC actions. The Company's only FDA approved product is cilta-cel, which was approved on February 28, 2022 under the trademark CARVYKTI™ for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The Company is party to a collaboration agreement with Janssen Biotech, Inc., upon which the Company depends for the development, manufacturing and commercialization of CARVYKTI™ and pursuant to that collaboration, the Company has established a manufacturing facility in the United States for the U.S. commercial supply of CARVYKTI™ and is in the process of establishing additional manufacturing capabilities in Belgium to grow its manufacturing reach. As a result, while the Company currently relies heavily on Janssen to launch and market CARVKTI™, the Company does not expect any PRC governmental actions would materially impact the development, manufacturing or commercialization of CARVYKTITM in its primary markets. In addition, and in accordance with analysts models, the Company believes that the majority of the value of its securities is derived from the development and commercialization of cilta-cel in the U.S., European Unition and other non-PRC markets. All of the Company's earnings for CARVYKTI™ to date are through the Janssen

collaboration and are generated in non-PRC markets and the Company does not expect this product to generate any significant future earnings in the PRC. In addition, the intellectual property needed to commercialize CARVYKTI™ in the U.S. is owned by the Company's subsidiary in the U.S. and the intellectual property needed to commercialize CARVYKTI™ in non-U.S. and non-PRC markets is owned by the Company's subsidiary in Ireland. Accordingly, the Company does not believe that its securities could be rendered worthless solely due to actions taken by PRC governmental authorities.

5. We note that, on May 4, 2022, the SEC conclusively listed you under the Holding Foreign Companies Accountable Act. Please provide prominent disclosure that your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and how the Holding Foreign Companies Accountable Act and related regulations will affect your company. In addition, disclose that trading in your securities may be prohibited under the Holding Foreign Companies Accountable Act if the PCAOB determines that it cannot inspect or investigate completely your auditor, and that as a result an exchange may determine to delist your securities. For additional information, refer to https://www.sec.gov/hfcaa.

Response to Comment 5:

In response to the Staff's comment, the Company will add the following disclosure at the onset of Part 1 of the Amended 20-F:

"The Holding Foreign Companies Accountable Act

On December 16, 2021, the Public Company Accounting Oversight Board (the "PCAOB") issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by local authorities. The Holding Foreign Companies Accountable Act (the "HFCA Act"), was signed into law on December 18, 2020. In accordance with the HFCA Act, trading in our ADSs on a national securities exchange or in the over-the-counter trading market in the United States may be prohibited if the PCAOB determines that it cannot inspect or fully investigate our auditor for three consecutive years beginning in 2021, and, as a result, an exchange may determine to delist our ADS.

On December 2, 2021, the SEC adopted final amendments implementing the disclosure and submission requirements under the HFCA Act, pursuant to which the SEC will (i) identify an issuer as a "Commission-Identified Issuer" if the issuer has filed an annual report containing an audit report issued by a registered public accounting firm that the PCAOB has determined it is unable to inspect or investigate completely because of the position taken by the authority in the foreign jurisdiction and (ii) impose a trading prohibition on the issuer after it is identified as a Commission-Identified Issuer for three consecutive years. In addition, on June 22, 2021, the U.S. Senate passed a bill on the Accelerating Holding Foreign Companies Accountable Act (the "AHFCAA"), which would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on a U.S. stock exchange if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. On February 4, 2022, the U.S. House of Representatives passed a bill which contained, among others, an identical provision. If this provision is enacted into law and the number of consecutive non-inspection years required for triggering the prohibitions is reduced from three to two, then the time period before the issuer's securities may be prohibited from trading or delisted could be reduced. On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission (the "CSRC") and the Ministry of Finance of the People's Republic of China, taking the first step toward opening access

for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. While significant, the Statement of Protocol is only a first step. Uncertainties still exist as to whether and how this new Statement of Protocol will be implemented.

Our auditor for the fiscal years ended December 31, 2021 and 2020, Ernst & Young Hua Ming LLP, is an independent registered public accounting firm that issues the audit reports included elsewhere in this annual report. The PCAOB identified Ernst & Young Hua Ming LLP as one of the registered public accounting firms that the PCAOB is unable to inspect or investigate completely and we were conclusively identified as a "Commission-Identified Issuer" on May 4, 2022. The fact that the PCAOB has been and currently is unable to inspect Ernst & Young Hua Ming LLP could deprive investors of the benefits of such inspections and cause our securities to be delisted under the HFCA Act and the AHFCAA. On May 3, 2022, our Audit Committee (i) resolved that Ernst & Young Hua Ming LLP would resign as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to be filed with the SEC, effective on June 1, 2022 and (ii) approved the engagement of Ernst & Young LLP, located in the United States, as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting for the fiscal year ended December 31, 2022 to be filed with the SEC and the Company subsequently entered into an engagement letter with Ernst & Young LLP. However, there are no guarantees that engaging Ernst & Young LLP will remove us from being a "Commission-Identified Issuer". Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and make any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act.

The delisting of our securities, or the threat of such securities being delisted, may materially and adversely affect the value of your investment. For a detailed description of the related risks, see "—D. Risk Factors—Risks Related to Doing Business in China— The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for three consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022, or two consecutive years if the AHFCAA is enacted. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections." See "—D. Risk Factors—Risks Related to Doing Business in China." Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and making any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act."

Additionally, the Company respectfully wishes to note for the Staff that although on May 4, 2022, the SEC conclusively listed the Company under the Holding Foreign Companies Accountable Act, on May 3, 2022,

our Audit Committee (i) resolved that Ernst & Young Hua Ming LLP would resign as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to be filed with the SEC, effective on June 1, 2022 and (ii) approved the engagement of Ernst & Young LLP, located in the United States, as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to ver financial reporting for the fiscal year ended December 31, 2022 to be filed with the SEC and the Company subsequently entered into an engagement letter with Ernst & Young LLP.

6. Clearly disclose how you will refer to the holding company and subsidiaries when providing the disclosure throughout the document so that it is clear to investors which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations. For example, disclose, if true, that your subsidiaries conduct operations in China.

Response to Comment 6:

In response to the Staff's comment, the Company will revise the disclosure on page 1 of the Amended Form 20-F as follows:

"In this Annual Report on Form 20-F, unless otherwise indicated or the context otherwise requires, "Legend Biotech" refers to Legend Biotech Corporation, a Cayman Islands holding company, "PRC subsidiaries" refer to Legend Biotech's subsidiaries incorporated in the PRC (as defined below) and "we," "us," "our," and the "Company" refer to Legend Biotech and its consolidated subsidiaries. References to "GenScript" or "Genscript" refer to Genscript Biotech Corporation, our majority stockholder."

The Company will also revise corresponding references to the holding company and subsidiaries throughout the document so it is clear which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations in the Amended 20-F.

7. Provide a clear description of how cash is transferred through your organization. Disclose your intentions to distribute earnings. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary have made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors.

Response to Comment 7:

In response to the Staff's comment, the Company will add the following disclosure at the onset of Part 1 of the Amended 20-F:

"Dividends and other distributions

As of the date of this Amendment No. 1, we have not previously declared or paid any cash dividend or dividend in kind, and we have no plan to declare or pay any dividends in the near future on its ordinary shares or the ADSs. We currently intend to apply any future earnings to fund the clinical development of cilta-cel, fund the construction and expansion



of our manufacturing facilities, fund the commercialization of CARVYKTI and fund the development of our pipeline programs, as well as for working capital and other general corporate purposes.

Legend Biotech is a holding company with no operations of its own. We conduct our operations through our subsidiaries, including our PRC subsidiaries. If the PRC government deems that any of our business operations carried out by our PRC subsidiaries were to be restricted or prohibited from investment by non-PRC investors in the future, we may be required to stop our business operations in the PRC and we could be subject to material penalties or be forced to relinquish our interests in the affected operations. Such events could result in a material change in our operations and a material change in the value of our securities, including causing the value of such securities to significantly decline. As we have incurred net losses and negative cash flow from operations historically, none of our subsidiaries have declared or paid any dividends or distributions to Legend Biotech or any investors as of the date of this Amendment No. 1. Instead, we have primarily relied on upfront and milestone payments and interest-bearing borrowings from Janssen Biotech, Inc. under our collaboration and license agreement, proceeds from public offerings and private placements of equity securities, and capital contributions from GenScript to fund business operations of our operating subsidiaries. All the net cash proceeds we receive from financial activities are first deposited in the bank account of Legend Biotech. The funds deposited into Legend Biotech's accounts are then transferred through Legend Biotech's applicable subsidiaries to each operating subsidiary to meet its working capital needs primarily through capital contributions or intercompany loans. For the years ended December 31, 2020 and 2021, Legend Biotech transferred \$61 million and \$460 million, respectively, through such capital contributions or intercompany loans.

According to the Foreign Investment Law of the People's Republic of China and its implementing rules, which jointly established the legal framework for the administration of companies invested by non-PRC investors, a non-PRC investor may, in accordance with other applicable laws, freely transfer into or out of China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of China in RMB or any non-RMB currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the People's Republic of China and other PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the PRC subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our PRC subsidiaries may allocate a portion of their after-tax profits based on PRC accounting standards to a discretionary reserve fund. See "-D. Risk Factors-Risks Related to Doing Business in China-Our business may be significantly affected by the newly enacted Foreign Investment Law and the "negative list."

RMB is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their potential future renminbi



revenues to pay dividends to us. The PRC government imposes controls on the convertibility of RMB into non-RMB currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of non-RMB currency may then restrict the ability of our PRC subsidiaries to remit sufficient non-RMB currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our non-RMB-currency-denominated obligations. The renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes cross-board direct investment and non-RMB currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase non-RMB currency for settlement of "current account transactions," including payment of dividends to us, without the approval of the State Administration of Foreign Exchange of China ("SAFE") by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase non-RMB currencies in the future for current account transactions. The PRC government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in renminbi to fund our business activities outside of China or pay dividends in non-RMB currencies to holders of our securities. In the PRC, foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain non-RMB currency through debt or equity financing for our subsidiaries. In addition, ADS holders may potentially be subject to PRC taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes. See "-D. Risk Factors-Risks Related to Doing Business in China-Dividends we receive from our subsidiaries located in the PRC may be subject to PRC withholding tax, which could materially and adversely affect the amount of dividends, if any, we may pay our shareholders" and "Item 10. Additional Information-E. Taxation-PRC Taxation" for further information."

8. Disclose each permission or approval that you or your subsidiaries are required to obtain from Chinese authorities to operate your business and to offer securities to foreign investors. State whether you or your subsidiaries are covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency that is required to approve your operations, and state affirmatively whether you have received all requisite permissions or approvals and whether any permissions or approvals have been denied. Please also describe the consequences to you and your investors if you or your subsidiaries: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future.

Response to Comment 8:

In response to the Staff's comment, the Company will add the following disclosure at the onset of Part 1 of the Amended 20-F:



"Permissions Required from the PRC Authorities for Our Operations

Each of our PRC subsidiaries is required to obtain, and has obtained, a business license issued by local counterparts of the State Administration for Market Regulation, or the SAMR. As of the date of this Amendment No. 1 and to our knowledge, our PRC subsidiaries have obtained the requisite licenses and permits from the PRC government authorities that are material for their business operations in China. However, given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by government authorities, we cannot assure you that we have obtained all the permits or licenses required for conducting our business in the PRC.

In connection with our previous issuance of securities to investors in stock markets outside the PRC, under current PRC laws, regulations and regulatory rules, as of the date of this Amendment No. 1, we and our PRC subsidiaries, (i) are not required to obtain permissions from the CSRC, (ii) are not required to go through cybersecurity review by the Cyberspace Administration of China, or the CAC, and (iii) to our knowledge, we have not received or were denied such requisite permissions by any PRC authority. However, the PRC government has recently indicated an intent to exert more oversight and control over offerings that are conducted outside the PRC and/or investment by non-PRC investors in issuers with operations in China.

We have been closely monitoring regulatory developments in China regarding any necessary permissions or approvals from the CSRC, the CAC or other PRC regulatory authorities for our operations in China. However, there are uncertainties as to the related interpretation and implementation of regulatory requirements, and the biopharmaceutical industry in the PRC is highly regulated and such regulations are subject to change. Therefore, it is uncertain whether we or our PRC subsidiaries will be required to obtain additional approvals, licenses, or permits, or complete additional filing procedures in connection with our business operations pursuant to the evolving PRC laws and regulations, and whether we would be able to obtain and renew such approvals, licenses, or permits, or complete such filing procedures in a timely manner or at all. Any failure by us or our PRC subsidiaries, even inadvertently, to maintain compliance with applicable PRC laws and regulations, or obtain and maintain required licenses and permits, in a timely manner or at all, may subject us or our PRC subsidiaries to administrative penalties, and the suspension or termination of our business activities in the PRC. See "—D. Risk Factors—Risks Related to Doing Business in China."

The Company will also revise the risk factor referenced below in the Amended 20-F as follows:

"The approval of, or filing or other procedures with, the CSRC or other governmental authority may be required in connection with issuing our equity securities outside of the PRC under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.

On August 8, 2006, six PRC regulatory agencies, including the China Securities Regulatory Commission, or the CSRC, promulgated the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors, or the M&A Rules, which became effective on September 8, 2006 and was amended on June 22, 2009. The M&A Rules, among other things, requires offshore SPVs formed for the purpose of a listing outside of the PRC and controlled by PRC companies or individuals, to obtain the CSRC approval prior to listing their securities on a stock exchange outside of the PRC. The application of this regulation remains unclear. Our PRC legal counsel has advised us that, based on their understanding of the current PRC laws, the CSRC approval was not required under the M&A Rules in the context of our initial public offering because the ownership structure of our PRC

subsidiaries was established by direct investment instead of through acquisition of equity interests or assets of any PRC domestic company by foreign entities as defined under the M&A Rules. However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel.

Furthermore, the recently issued Opinions on Strictly Cracking Down on Illegal Securities Activities emphasized the need to strengthen the supervision on listings outside of the PRC by companies with operations in China and provided that the special provisions of the State Council on issuance and listing of shares outside of the PRC by those companies limited by shares will be revised. There are still uncertainties regarding the interpretation and implementation of these Opinions, and further explanations or detailed rules and regulations with respect to these Opinions may be issued in the future which could impose additional requirements on us. On December 24, 2021, the CSRC issued the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (collectively, the "Draft Overseas Listing Regulations"), which has a comment period that expired on January 23, 2022. The Draft Overseas Listing Regulations require, among others, that PRC domestic companies that seek to offer and list securities in markets outside of the PRC, either through direct or indirect means, are required to file the required documents with the CSRC within three working days after its application for listing on a stock exchange outside of the PRC is submitted and report to CSRC after such offering and listing is completed.

As of the date of this Amendment No. 1, the Draft Overseas Listing Regulations are both still in draft forms and there are uncertainties regarding the final forms of the Draft Overseas Listing Regulations as well as the interpretation and implementation thereof after promulgation. As the CSRC may formulate and publish guidelines for filings in the future. In a Q&A released on its official website, the respondent CSRC official indicated that the proposed new filing requirement will start with new companies and the existing companies seeking to carry out activities like follow-on financing. As for the filings for the existing companies, the regulator will grant adequate transition period and apply separate arrangements. Given the substantial uncertainties surrounding the latest CSRC filing requirements at this stage, we cannot assure you that we will be able to complete the filings and fully comply with the relevant new rules on a timely basis, if at all.

In addition, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements on us. If it is determined in the future that approval and filing from the CSRC or other regulatory authorities or other procedures, including the cybersecurity review under the Measures for Cybersecurity Review and the Draft Data Security Regulations, are required for our offshore offerings, it is uncertain whether we can or how long it will take us to obtain such approval or complete such filing procedures and any such approval or filing could be rescinded or rejected. Any failure to obtain or delay in obtaining such approval or completing such filing procedures for our offshore offerings, or a rescission of any such approval or filing if obtained by us, would subject us to sanctions by the CSRC or other PRC regulatory authorities for failure to seek CSRC approval or filing or other government authorization for our offshore offerings. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the proceeds from our offshore offerings into China or take other

actions that could materially and adversely affect our business, financial condition, results of operations, and prospects, as well as the trading price of our listed securities."

Risks Related to Doing Business in China, page 57

9. Given the Chinese government's significant oversight and discretion over the conduct of your business, please revise to highlight separately the risk that the Chinese government may intervene or influence your operations at any time, which could result in a material change in your operations and/or the value of your securities. Also, given recent statements by the Chinese government indicating an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, acknowledge the risk that any such action could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of your securities to significantly decline or be worthless.

Response to Comment 9:

In response to the Staff's comment, the Company will add the following risk factor in the Amended 20-F:

"PRC governmental authorities may intervene or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs.

The PRC government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political and societal goals. The PRC government has recently published new policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could require us to seek permission from PRC authorities to continue to operate our business in the PRC, which could adversely affect our business, financial condition and results of operations, as well as adversely impact the value of the ADSs, causing them to significantly decline in value. Furthermore, recent statements made by the PRC government have indicated an intent to increase the government's oversight and control over offerings of companies with significant operations in China that are to be conducted in foreign markets, as well as foreign investment in issuers with operations in China like us. Any such action, once taken by the PRC government, could result in action taken by the PRC against our PRC subsidiaries and could significantly limit, delay or hinder our ability to offer or continue to offer securities to investors, or cause the value of such securities to significantly decline."

In addition, the Company respectfully wishes to clarify for the Staff that, while the PRC government's actions could impact the Company's pre-clinical research and development activities in China, the Company's ability to use the investigator initiated trial model for early clinical development of products being developed in China, biologics application approvals in China and product commercialization in China, the Company's business operations with regard to the development, manufacturing and sales of its lead product candidate, ciltacabtagene autolucel ("cilta-cel"), in its primary markets would not be materially affected by any such PRC actions. The Company's only FDA approved product is cilta-cel, which was approved on February 28, 2022 under the trademark CARVYKTITM for the treatment of adults with relapsed or refractory multiple myeloma who have received four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The Company is party to a collaboration

agreement with Janssen Biotech, Inc., upon which the Company depends for the development, manufacturing and commercialization of CARVYKTI[™] and pursuant to that collaboration, the Company has established a manufacturing facility in the United States for the U.S. commercial supply of CARVYKTI[™] and is in the process of establishing additional manufacturing capabilities in Belgium to grow its manufacturing reach. As a result, while the Company currently relies heavily on Janssen to launch and market CARVKTI[™], the Company does not expect any PRC governmental actions would materially impact the development, manufacturing or commercialization of CARVYKTI[™] in its primary markets. In addition, and in accordance with analysts models, the Company believes that the majority of the value of its securities is derived from the development and commercialization of cilta-cel in the U.S., European Unition and other non-PRC markets. All of the Company does not expect this product to generate any significant future earnings in the PRC. In addition, the intellectual property needed to commercialize CARVYKTI[™] in the U.S. is owned by the Company's subsidiary in the U.S. and the intellectual property needed to commercialize CARVYKTI[™] in non-U.S. and non-PRC markets is owned by the Company's subsidiary in Ireland. Accordingly, the Company does not believe that its securities could be rendered worthless solely due to actions taken by PRC governmental authorities.

The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting. . . , page 69

10. Update your disclosure to reflect that the Commission adopted rules to implement the HFCAA and that, pursuant to the HFCAA, the PCAOB has issued its report notifying the Commission of its determination that it is unable to inspect or investigate completely accounting firms headquartered in mainland China or Hong Kong. Moreover, please update this risk factor to account for the fact that the SEC conclusively identified you under the HFCAA on May 4, 2022.

Response to Comment 10:

In response to the Staff's comment, the Company will revise the referenced risk factor in the Amended 20-F, as follows:

"The audit report included in this Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB, and, as such, our investors are deprived of the benefits of such inspection. Our ADSs may be delisted under the HFCA Act if the PCAOB is unable to inspect our auditors for three consecutive years as we were identified by the SEC as a Commission-Identified Issuer on May 4, 2022, or two consecutive years if the AHFCAA is enacted. The delisting of our securities, or the threat of our securities being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives investors of the benefits of such inspections.

As an auditor of U.S. publicly traded companies and a PCAOB-registered accounting firm, the independent registered public accounting firm that issued the audit report included in this Annual Report is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Because our auditor is located in the PRC, a jurisdiction where the



PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

PCAOB inspections are able to identify deficiencies in the inspected firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating our auditor's audits and quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections of our auditor.

The inability of the PCAOB to conduct an inspection of our auditor makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Accordingly, investors may have a lower level of confidence in our reported financial information and procedures and the quality of our financial statements than if our auditor were subject to PCAOB inspections.

Further, U.S. legislators and regulators have in recent years voiced concerns about risks associated with investing in companies that are based in or have substantial operations in emerging markets, including China. In particular, lawmakers have highlighted the increased risks associated with companies whose independent auditors are unable to be inspected by the PCAOB. As part of this continued focus in the United States on access to audit and other information currently protected by national law, in particular China's, on December 18, 2020, the U.S. president signed the HFCA Act into law. On November 5, 2021, the SEC approved the PCAOB's Rule 6100, Board Determinations Under the "Holding Foreign Companies Accountable Act." Rule 6100 provides a framework for the PCAOB to use to determine whether it is unable to inspect or investigate registered public accounting firms located in a jurisdiction outside of the United States because of a position taken by one or more authorities in that jurisdiction. On December 2, 2021, the SEC adopted final rules implementing the HFCA Act.

The HFCA Act requires the SEC to identify and maintain a list of U.S. listed companies whose audit reports are prepared by auditors that the PCAOB is unable to inspect or investigate completely because of restrictions imposed by the authorities in a jurisdiction outside of the U.S.. The HFCA Act also requires SEC-identified public companies to (i) submit documentation establishing that the company is not owned or controlled by a governmental entity in the jurisdiction that restricts PCAOB inspections and (ii) make certain additional disclosures in their SEC filings regarding, among other things, the fact that the PCAOB is unable to inspect its audit firm, the percentage of the company's shares owned by governmental entities in such jurisdiction outside of the U.S., whether governmental entities in such jurisdiction outside of the U.S., whether governmental entities in such jurisdiction outside of the U.S., whether governmental entities in such jurisdiction outside of the U.S., and whether there are any charters of the Chinese Communist Party members on the company's organizational documents (including the text of any such charter). For issuers remaining on the SEC-identified companies list for three consecutive years, the securities of such company would be prohibited from trading on a U.S. national securities exchange, such as The Nasdaq Global Select Market, or in U.S. over-the-counter markets.

On June 22, 2021, the U.S. Senate passed a bill which, if passed by the U.S. House of Representatives and signed into law, would reduce the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three



years to two. On December 16, 2021, the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by local authorities. The PCAOB made these determinations pursuant to PCAOB Rule 6100, which provides a framework for how the PCAOB fulfills its responsibilities under the HFCA Act. On February 4, 2022, the U.S. House of Representatives passed the America Competes Act of 2022, which includes the exact same amendments as the bill passed by the Senate. The America Competes Act however includes a broader range of legislation not related to the HFCA Act in response to the U.S. Innovation and Competition Act passed by the Senate in 2021. The U.S. House of Representatives and U.S. Senate will need to agree on amendments to these respective bills to align the legislation and pass their amended bills before the President can sign the amended bills into law. It is unclear when the U.S. Senate and U.S. House of Representatives will resolve the differences in the U.S. Innovation and Competition Act and the America Competes Act of 2022 bills currently passed, or when the U.S. President will sign on the bills to make the amendment into law, or at all. If this provision is enacted into law and the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act is reduced from three years to two, then our shares and ADSs could be prohibited from trading in the United States in 2023.

On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission and the Ministry of Finance of the People's Republic of China, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. The Statement of Protocol gives the PCAOB sole discretion to select the firms, audit engagements and potential violations it inspects and investigates and put in place procedures for PCAOB inspectors and investigators to view complete audit work papers with all information included and for the PCAOB to retain information as needed. In addition, the Statement of Protocol grants the PCAOB direct access to interview and take testimony from all personnel associated with the audits the PCAOB inspects or investigates. While significant, the Statement of Protocol is only a first step. Uncertainties still exist as to whether and how this new Statement of Protocol will be implemented.

Our auditor for the fiscal years ended December 31, 2021 and 2020, Ernst & Young Hua Ming LLP, is an independent registered public accounting firm that issues the audit reports included elsewhere in this annual report. Ernst & Young Hua Ming LLP is subject to the determinations announced by the PCAOB, and the PCAOB has been and currently is unable to inspect Ernst & Young Hua Ming LLP and we were conclusively identified as a "Commission-Identified Issuer" on May 4, 2022. On May 3, 2022, our Audit Committee (i) resolved that Ernst & Young Hua Ming LLP would resign as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting to be filed with the SEC, effective on June 1, 2022 and (ii) approved the engagement of Ernst & Young LLP, located in the United States, as the Company's independent registered public accounting firm for the audits of the Company's financial statements and internal control over financial reporting for the fiscal year ended December 31, 2022 to be filed with the SEC and the Company subsequently entered into an engagement letter with Ernst & Young LLP. However, there are no guarantees that engaging Ernst & Young LLP will remove us from being a "Commission-Identified Issuer". Ernst & Young LLP must still be able to produce any audit work papers upon any PCAOB inspection or investigative demand and making any relevant audit personnel available to the PCAOB upon inspection or investigative demand. The failure of Ernst & Young LLP to meet any of its legal or professional obligations with respect to PCAOB inspection and investigative demands, or the failure of the Ernst & Young LLP to



comply with all applicable audit standards could result in significant liability for us or result in the delisting of our securities pursuant to the HFCA Act.

The enactment of the HFCA Act and AHFCAA and the implications of any additional rulemaking efforts to increase U.S. regulatory access to audit information in China could cause investor uncertainty for affected SEC registrants, including us, and the market price of our ADSs could be materially adversely affected. Any actions that Legend Biotech takes in response to the HFCA Act and compliance with the requirements of the HFCA Act for so long as Legend Biotech remains an SEC-identified company may require Legend Biotech to incur additional legal, accounting and other expenses, which may be significant."

Operating And Financial Review And Prospects Operating Results, page 153

11. Please expand in future filings to include a more robust disclosures for your operating result, including more disaggregated disclosures about the significant components of revenues or expenses and their change drivers, both quantitatively and qualitatively. More specifically on the research and development expenses, considering the significant balances, the existence of other phase 3 trials, as well as the impact from the Janssen agreement, please provide more disaggregated disclosures by product (group), and or by nature of costs. Please also disclose specifically the amount of research and development expenses incurred by yourself as well as the amount payable to Janssen under your license and collaboration agreement with Janssen. In that regard, you disclosed at page F-49 that you took a total of \$119.7 million funding advances in 2021 by reducing the same amount of other payables due to the collaborator. Refer to Item 303 of Regulation S-K.

Response to Comment 11:

The Company acknowledges the Staff's comment and will undertake to provide more robust disclosure in future filings.

If you have any questions regarding this submission, please contact Divakar Gupta at +212 479-6474 (dgupta@cooley.com) or Mark Ballantyne at +703 456-8084 (mballantyne@cooley.com).

Thank you for your time and attention.

Sincerely yours,

By: <u>/s/ Mark Ballantyne</u> Mark Ballantyne

cc: Ying Huang, Chief Executive Officer Marc L. Harrison, General Counsel Legend Biotech Corporation

Divakar Gupta, Partner **Cooley LLP**