September 1, 2023

Songlin Song
Chief Executive Officer
Zhengye Biotechnology Holding Limited
No.1 Lianmeng Road, Jilin Economic & Technical Development Zone
Jilin City, Jilin Province, China

Re: Zhengye

Biotechnology Holding Limited

Draft Registration

Statement on Form F-1

Submitted August 4,

2023

CIK No. 0001975641

Dear Songlin Song:

 $\label{eq:commutation} \text{We have reviewed your draft registration statement and have the following comments. In}$ 

some of our comments, we may ask you to provide us with information so we may better  $% \left( 1\right) =\left( 1\right) +\left( 1\right$ 

understand your disclosure.

 $\hbox{ Please respond to this letter by providing the requested information and either submitting }$ 

an amended draft registration statement or publicly filing your registration statement on

 ${\tt EDGAR.}$  If you do not believe our comments apply to your facts and circumstances or do not

believe an amendment is appropriate, please tell us why in your response.

 $\hbox{ After reviewing the information you provide in response to these comments and your } \\$ 

amended draft registration statement or filed registration statement, we may have additional

comments.

Draft Registration Statement on Form F-1, submitted August 4, 2023

Prospectus Summary
Our Corporate Structure, page 1

1. We note your disclosure that you are not a Chinese operating company but a Cayman

Islands holding company with operations conducted by your subsidiaries. Please provide

a cross-reference to your detailed discussion of risks facing the company and the offering as a result of your organizational structure.

2. We note your disclosure that you are not currently involved in any investigations on cybersecurity review initiated by any PRC regulatory authority and that, as confirmed by your PRC counsel, you believe you are not subject to the Cybersecurity Review

believe you are not subject to the Cybersecurity Review Songlin Song

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 $\hbox{\tt Measures. Please include a discussion of how such data security} \\ \\ \hbox{\tt measures may impact the}$ 

company's ability to conduct its business, accept foreign investments, or list on a U.S. or

other foreign exchange if you were found to be subject to such regulatory actions. Please  $\,$ 

also include a similar discussion for anti-monopoly concerns.

3. You state that as of the date of the prospectus, no cash transfer or transfers of other assets

has occurred among the Company and any of its subsidiaries. Please also state if there  $\,$ 

have been any transfers, dividends, or distributions between the subsidiaries and, if so,

please quantify the amounts.
Risks Relating to Our Business and Industry, page 31

4. We note your disclosure on page 56 that approximately 90.5% and 85.6% of the operating  $\,$ 

entity's revenues for the years 2022 and 2021 respectively were derived from Swine

vaccines. To the extent that any such risks exist, please revise the disclosure in this

section to describe the risks associated with deriving such a significant percentage of

revenue from vaccines for one type of animal.

Use of Proceeds, page 49

5. Please revise the use of proceeds section to provide with specificity the types of  ${\rm R\&D}$ 

 $% \left( 1\right) =\left( 1\right) \left( 1\right)$  projects the operating entity plans to conduct, which products they relate to, and, to the

extent the operating entity intends to utilize the proceeds from this offering to conduct

 $\,$  pre-clinical or clinical work, please specify how far in the development of its products the

operating entity expects to reach with the proceeds of the offering.

6. Please revise your use of proceeds section to provide the approximate dollar amount

intended to be used for each purpose.

7. Please revise your use of proceeds section to provide more specificity about the

 $\,$  new workshops the operating entity intends to build using the proceeds from this offering,

such as any planned locations or the anticipated size of these workshops.

Dividend Policy, page 50

8. Please revise your disclosure in this section to note that the operating entity intends to

distribute a dividend in the amount of RMB 55,104,000 before May 2024, as you disclose

on on the cover page and elsewhere throughout the registration statement.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview, page 55

FirstName LastNameSonglin Song

9. We note you provide the RMB to USD conversion for fiscal year end 2022. Please also

Comapany NameZhengye

provide Biotechnology

the same conversion Holding

for fiscal Limited

year end 2021, here and

throughout the filing, so

that 1,

September investors can 2make proper comparisons.

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Zhengye Biotechnology Holding Limited

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 ${\tt FirstName} \ {\tt LastName}$ 

Key Components of Results of Operations

Research and development expenses, page 57

10. On pages 82-84, you refer to multiple collaboration arrangements with universities and

research institutions as well as active participation in research projects sponsored by the

government of Jilin Province PRC during 2021-2023. Please explain the nature of

your active participation with these third parties, particularly the research and  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

development performed by the 49 employees in your R&D department and

associated costs are funded. Also, describe key terms governing these collaboration  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

arrangements, including options allowing you to license intellectual property developed under these arrangements and related financial obligations for achievement of development, regulatory or sales milestones as well as royalty payments based on product sales. In addition, explain how you plan to invest RMB90 million to develop multiple veterinary vaccines from net proceeds of the planned offering as discussed on page 77, specifying the extent to which this planned development will involve third parties such as Harbin Veterinary Research Institute, Shanghai Veterinary Research Institute, China Agricultural University, Jilin University and Nanjing Agricultural University. Provide a breakdown of this investment by recipient and nature of planned product development. Revise your disclosures accordingly. Overview of China's Veterinary Vaccine Market Market Size of Veterinary Vaccine in China, page 66 11. You state that the market size of the Chinese veterinary market increased from RMB 12.6 billion in 2018 to RMB 16.5 billion in 2022 and that it is expected to further increase to RBM 21.2 billion in 2026. Please provide the market sizes in USD here and on pages 71, 72, and 73. National policies of animal epidemic detection and prevention, page 67 You list various policies of epidemic detection and prevention that you claim have strengthened animal epidemic prevention and control measures. Please explain with specificity how the policies listed have strengthened animal epidemic prevention and control measures. Analysis of Domestic Top Players' Product Portfolio, page 68 Please revise your disclosure to identify the names of the companies listed in Frost & Sullivan's analysis. Ranking of Revenue of China's Veterinary Vaccine Companies, page 69 14. We note your disclosure that in 2022, "ZYBIO generated revenue of RMB[] 300 million." Please reconcile this figure with your disclosure on page 3 stating that the operating entity's revenue reached approximately RMB 260.3 million for the fiscal year Songlin Song Zhengye Biotechnology Holding Limited September 1, 2023 Page 4 ended December 31, 2022. Historical and Forecasted Market Size of Porcine Vaccine in China, 2018-2026E, Please identify the entity listed as "CVDA" with more specificity in the first instance. Additionally, we note your disclosure that the source for this graphic, and other data in your registration statement, is listed as "Expert Interview." To the extent you are relying on the analysis or report of an expert, please disclose the identity of the expert and file the written consent of that expert as an exhibit to this registration

statement or, alternatively,

please explain why you are not required to do so. Refer to Rule 436 of the Securities Act

for quidance.

Analysis of Domestic Top Players' Pet Vaccine Portfolio, page 74

You state that Jilin Zhengye ("ZYBIO") has been granted two approvals for clinical trials

of its veterinary vaccines. Please describe the status of these clinical trials, including, but

not limited to, where the trials are being conducted, whether any third parties are assisting

with the trials, the structure of the trials, and whether any results

have been observed. Business Competitive Strengths Diversified products, page 75 Please disclose which animal or animals the Rabies Vaccine, 17. Inactivated (Strain Flury LEP) vaccine is designed to treat. Strong research and development capabilities, page 75 Please revise your disclosure to state the total aggregate amount to date that has been paid to each of the parties listed in this section pursuant to the collaboration agreements. Growth Strategies Develop high-demand products and expand the operating entity's business..., page 76 You state that your operating entity intends to develop high-demand products and you list various products that appear to be in development. Please include a short description of each vaccine's indication and whether each vaccine is in pre-clinical or clinical trials. Also, please provide justification for the statement that the operating entity's products are in "high-demand." Please clarify whether the Ministry of Agriculture and Rural Affairs of the PRC is the FirstName LastNameSonglin Song entity that has provided the approvals for the products listed in this section. Additionally, Comapany NameZhengye please clarify if anyBiotechnology of the productsHolding listed inLimited this section have been approved for sale or whether further September 1, 2023 Pageclinical development will be required. 4 FirstName LastName Sonalin Sona FirstName LastNameSonglin Zhengye Biotechnology Holding Limited Comapany 1, September NameZhengye Biotechnology Holding Limited 2023 September Page 5 1, 2023 Page 5 FirstName LastName Expand the operating entity's sales and distribution network, page 76 You state that the operating entity plans to expand its sales and distribution network to enter new geographic markets. Please identify such geographic markets. Increase R&D investment, page 77 Please revise your disclosure to provide further detail regarding the research and development that has been conducted to date, if any, for each of the products listed in this section. To the extent that the operating entity has not begun any pre-clinical or clinical work for any of the vaccines listed in this section, please revise your disclosure accordingly. Products, page 77 23. You state that the operating entity has a total of 43 veterinary

portfolio, 43 of which are sold domestically and five of which are

We note your disclosure that the operating entity is "researching

Peritonitis Subunit Vaccine, Feline Leukemia and Feline

Please identify which vaccines are sold internationally and where they

Additionally, please indicate in the table which specific products are

vaccines in its product

sold internationally.

sold internationally.

about Feline Infectious

are being sold.

Immunodeficiency Disease

Duplex mRNA Vaccine, and Feline GnRH Immunocontraceptive Vaccine."

provide further details about the research the operating entity is conducting with regard to

these vaccines.

25. You state that the operating entity has been granted approval to conduct clinical trials for

Feline Herpes virus, Feline Calicivirus and Feline Panleukopenia Triple Vaccine,

Inactivated on June 15, 2021. Please state whether the operating entity has begun clinical

trials or state when they are expected to begin.

26. We note your disclosure that the operating entity is conducting "animal experiments to

assess the immunity effectiveness of newly developed mRNA vaccines." Please provide  $% \left( 1\right) =\left( 1\right) \left( 1$ 

further details about the animal experiments the operating entity is conducting.

Regulatory Approvals for the Company's Products, page 80

27. We note the chart on page 80 listing the regulatory approvals received by the operating

entity and the validity dates for each. Please explain what is meant by the term  $^{"}$ Long

term" in this chart.

28. Please revise your table here to explain which regulatory approvals correspond with which

products. Additionally, please provide narrative disclosure here to provide context

regarding what these regulatory approvals allow you to do with your products.

29. Please disclose whether you have received any regulatory approvals to sell your products

internationally.

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Please

Suppliers, page 81

30. We note your disclosure that the operating entity's suppliers provide raw materials, such

as "experimental animal." Please revise your disclosure to explain what is meant by

"experimental animal" in this instance.

R&D, page 82

31. You state that the operating entity currently has collaboration agreements with Harbin

Veterinary Research Institute, Shanghai Veterinary Research Institute, and China

Agricultural University and you broadly describe some key terms on page 83. Please

disclose whether all of the collaborative research agreements with universities and  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

research institutions referenced here are identical and have the same terms. To the extent  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

that any agreements are unique, please disclose the material terms of those agreements.

including a description of each party's rights and obligations, a quantification of any

payment obligations, including any royalty fees or milestone payments, and a summary of

the term and termination provisions. To the extent that any of the collaboration  $\ensuremath{\mathsf{Collaboration}}$ 

agreements differ from the Form of Collaborative Research and Development Agreement  $\,$ 

attached as Exhibit 10.8, please file the agreements as exhibits in accordance with Item

 $601\mbox{(b)}\mbox{(10)}$  of Regulation S-K or, alternatively, explain why you are not required to do so.

32. We note your disclosure that the operating entity has been "actively participating in

research projects sponsored by the government of Jilin Province, PRC." Please disclose

whether any of the research projects involved the execution of collaboration agreements  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

with the government of Jilin Province, PRC or any other third parties. If so, please

disclose the material terms of those agreements and attach them as

33. We note your disclosure that the operating entity "secures its exporting distributors mainly

through Alibaba.com." Please provide further details about how the

entity secures its distributors through Alibaba.com.

Regulations

Regulations Related to Veterinary Drugs Production and Operation, page 95

34. Please provide disclosure in this section about the process by which the Ministry of

Agriculture and Rural Affairs of the PRC issues a Registration Certificate of New  $\,$ 

Veterinary Drugs, which you reference on page 9. Additionally, please explain whether a

FirstName LastNameSonglin Song

Registration Certificate of New Veterinary Drugs allows the operating entity to market

Comapany NameZhengye

and sell its productsBiotechnology

domestically orHolding

whetherLimited

any additional testing or

approvals are

required

September to market

1, 2023 Page 6and sell the products.

 ${\tt FirstName \ LastName}$ 

Songlin Song

FirstName LastNameSonglin Song

Zhengye Biotechnology Holding Limited

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FirstName LastName

Management, page 104

35. We note your disclosure regarding the "notice of criticism towards Mr. Han, which was

recorded in the Securities and Futures Market Integrity File on May  $18,\ 2022.$ " Please

revise your disclosure to explain the consequences, if any, of the notice of criticism  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

described here. To the extent that this notice of criticism may have a negative impact on

the value of the Ordinary Shares or the operating entity's business, please revise your risk

factor disclosure accordingly.

Compensation of Directors and Executive Officers, page 107

36. Please revise your disclosure to provide the amount of compensation paid to each of

 $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

are not required to do so. Refer to Item 4a of Form F-1 and Item 6B of Form 20-F for  $\,$ 

guidance.

Notes to the Consolidated Financial Statements

2. Summary of Significant Accounting Policies

Noncontrolling interests, page F-14

37. Please revise your disclosure to identify the noncontrolling interests as 15.2439% held by

 $\label{eq:conomic} \mbox{Jilin Economic and Technological Development Zone Economic and Technological}$ 

Development General Corporation, 0.9146% held by Jilin Jinqiao Investment Co. Ltd and

0.0001% held by Yufeng Liu.

General

38. Please supplementally provide us with copies of all written communications, as defined in

Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf,

present to potential investors in reliance on Section  $5\left(d\right)$  of the Securities Act, whether or

not they retain copies of the communications.

You may contact Franklin Wyman at 202-551-3660 or Daniel Gordon at 202-551-3486 if

contact Doris Stacey Gama at 202-551-3188 or Joshua Gorsky at 202-551-7836 with any other questions.

Sincerely,

Division of

Corporation Finance

Office of Life

Sciences

cc: Ying Li, Esq.