November 15, 2021

Robert Hershberg, M.D., Ph.D. Chief Executive Officer HilleVax, Inc. 75 State Street Suite 100 - #9995 Boston, MA 02109

> Re: HilleVax, Inc. Draft Registration

Statement on Form S-1

Submitted October

19, 2021

CIK No. 0001888012

Dear Dr. Hershberg:

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

understand your disclosure.

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

 $\ensuremath{\mathsf{EDGAR}}.$  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.

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

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

comments.

Robert Hershberg, M.D., Ph.D.

FirstName LastNameRobert Hershberg, M.D., Ph.D.

HilleVax, Inc.

Comapany 15,

November NameHilleVax,

2021 Inc.

November

Page 2 15, 2021 Page 2

FirstName LastName

Draft Registration Statement submitted on October 19, 2021

Overview, page 1

1. We note your disclosure that you plan to initiate a Phase 2b clinical trial for HIL-214.

Please revise to disclose whether you will need to submit an investigational new drug

application to the FDA before you can begin that trial and clarify when you intend to

make such submission, if required. We also note your disclosure on page 117 that you

have designed your planned Phase 2b clinical trial based on learnings from the NOR-211

Phase 2b study as well as preliminary feedback Takeda received from the FDA and

European Medicines Agency. Given this disclosure, please also indicate, if true, that the  $\,$ 

FDA may not accept or view the clinical trial results from Takeda, other third parties, or

non-U.S. regulators as sufficient to allow you to advance to a Phase 2b study and may

require you to conduct additional trials before proceeding to a Phase 2b trial.

Summary, page 1

Please revise your disclosure to include a pipeline table illustrating your clinical

development program for HIL-214. Please balance your disclosure in the Summary to clarify that the nine clinical trials of HIL-214 to date have been conducted by Takeda and its predecessor,

LigoCyte

Pharmaceuticals, Inc., and that you have not yet completed any

clinical trials or submitted an IND or its equivalent to the applicable regulatory agencies.

HIL-214 clinical data and development plan, page 4

We refer to your disclosure on page 4 that HIL-214 s adverse event profile was observed

to be similar to that of approved alum-adjuvanted vaccines. Please revise to expand your

disclosure of any adverse events that were observed in the clinical trials in both infants

and adults.

Commercial opportunity, page 5

We note your disclosure here and elsewhere in the registration statement that you believe

that Shingrix, a vaccine developed to prevent shingles, is a market analogue for HIL-214

for purposes of estimating your market opportunity. In an appropriate location in your

prospectus, please expand your discussion to support this statement.

Robert Hershberg, M.D., Ph.D.

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Comapany 15,

NameHilleVax, November

> 2021 Inc.

November

Page 3 15, 2021 Page 3

FirstName LastName

Our team and investors, page 6

We note that you identify a group of "leading investors" in your company in this section,

however, some of these investors do not appear to be among the principal stockholders

that are identified on page 168. Please relocate this disclosure from your prospectus

summary to your "Principal Stockholder" section. We note in this regard that the

identification of the pre-IPO investors in your prospectus summary may appear to suggest

that potential investors in your public offering consider investments made by the pre-IPO

investors as a factor in making an investment decision without knowing, among other

things, the amount of each pre-IPO investor s investment in total or on a per share basis,

their investment strategies or whether those investors will continue to hold their shares in

the future, as some of the pre-IPO investors may not be subject to the reporting

requirements of Section 16 of the Exchange Act, and investors in your public offering will

not necessarily know when some of the pre-IPO investors decide to sell any of their

shares. In addition to relocating this disclosure, please limit any textual description of your

pre-IPO investors in your "Principal Stockholders" section to the investors identified in

that table.

Summary of risks related to our business, page 7

We refer to your disclosure on pages 37 and 119 that a key element of your commercial

strategy is to receive advisory body recommendations for the use of HIL-214, particularly

from the Advisory Committee on Immunization Practices (ACIP) of the CDC. Please

include as a principal risk factor the risk to your business in the event your vaccine

candidate is not recommended by ACIP.

Risk factors, page 14

We note your disclosure on page 156 that the administrator of the 2022 Plan may, without

the approval of stockholders, amend any outstanding stock option or SAR to reduce its price per share, other than in the context of corporate transactions or equity

restructurings. Please include appropriate risk factor disclosure, including whether proxy

advisory firms could find such repricing without stockholder approval contrary to a

performance-based pay philosophy.

We face significant competition..., page 39

We refer to your disclosure relating to your competitors who are also developing a

vaccine for norovirus. Please disclose whether any of your competitors are also focused

on developing a vaccine consisting of VLPs representing the GI and GII genogroups of

norovirus. Please also disclose whether any of your competitors are also developing

pediatric vaccines for the prevention of norovirus-related illness.

Robert Hershberg, M.D., Ph.D.

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Comapany 15,

November NameHilleVax,

> 2021 Inc.

November

15, 2021 Page 4 Page 4

FirstName LastName

Our amended and restated certificate of incorporation and amended and restated bylaws..., page

We note your disclosure on page 74 that the forum selection in your 10. amended and restated

certificate of incorporation and bylaws may limit a shareholder's ability to bring a claim in

a judicial forum that it finds favorable for disputes with you and may discourage such

lawsuits. Please revise this risk factor to disclose that there is also a risk that your forum

selection provision may result in increased costs for investors to bring a claim.

Special note regarding forward-looking statements, page 80

We note your statement cautioning investors not to rely on forward-looking statements

and projections in your prospectus. These statements may imply an inappropriate

disclaimer of responsibility; therefore, please either remove the potential disclaiming

language or clearly state in this section that you are liable for such information.

Use of proceeds, page 82

Please revise to disclose how far the proceeds you plan to allocate 12. from the offering

toward the clinical development of HIL-214 will allow you to proceed with such

program. Refer to Instruction 3 to Item 504 of Regulation S-K. Management's discussion and analysis of financial condition and results of operations

Critical accounting policies and significant judgments and estimates, page 98

Once you have an estimated offering price or range, please explain to us how you

determined the fair value of the common stock underlying your equity issuances and the

reasons for any differences between the recent valuations of your common stock leading

up to the IPO and the estimated offering price. This information will help facilitate our

review of your accounting for equity issuances including stock compensation and

beneficial conversion features. Please discuss with the staff how to submit your response. Business, page 100

Please clarify the meaning of scientific or technical terms the first time they are used in

order to ensure that all investors will understand the disclosure. For

example, please
briefly explain what you mean by bivalent, immunogenicity and seroresponse rates.
Dose finding and formulation trials in adults, page 112

15. We refer to your disclosure of the dose finding and formulation trials and efficacy trials

conducted in adults starting on page 112. Please expand your disclosure of the scope and

design of the trials, including the size of each trial and the type of placebo used, whether  $\,$ 

the dose finding trials were powered for statistical significance,

whether any adverse side
effects were observed and to discuss the data from the results to
support the conclusions

drawn concerning immunogenicity, as applicable.

Robert Hershberg, M.D., Ph.D.

HilleVax, Inc.

November 15, 2021

Page 5

Safety results in infants and children, page 115

16. We note your disclosure on pages 115 and 116 of the adverse events and reactions

observed in infants, children and older adults in the NOR-202 and other clinical trials for

 $\mbox{\sc HIL-}{214}.$  Please revise to clarify the number of participants who experienced the adverse

effects referenced.

Phase 2b infant efficacy trial, page 117

17. We note your disclosure that subjects in your planned Phase 2b infant efficacy trial will

receive HIL-214 (50/150  $\,$  g GI.1/GII.4 VLP combination with 500  $\,$  g alum) in a two-

dose regimen delivered 28 to 56 days apart and that you have designed your planned  $\,$ 

Phase 2b clinical trial based on learnings from the NOR-211 Phase 2b study as well as  $\,$ 

preliminary feedback Takeda received from the FDA and European Medicines

Agency. We also note your disclosure on page  ${\bf 112}$  regarding the dosage and scheduling

for infants in the NOR-202 trial. If your dosage and scheduling in your Phase 2b infant  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left($ 

efficacy trial also will be based on data from NOR-202, please revise to make that clear

and indicate the dosing schedule for infants in NOR-202. Intellectual property, page 120  $\,$ 

18. We note your disclosure relating to the nine patent families of your patent

portfolio. Please clarify your disclosure to identify for each patent family the scope and  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

technology of each such patent family or patent application, the type of patent protection

(such as composition of matter, use or process), the applicable jurisdiction of the issued  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

foreign patents and foreign pending patent applications and expiration vears.

License agreement and clinical manufacturing and supply agreement, page 164

19. We note your disclosure that in connection with the Takeda License, you provided Takeda

with various investor rights, including pre-emptive rights, drag along rights, voting rights

and certain registration rights. Please clarify whether these rights will terminate upon the

closing of your public offering.

Principal stockholders, page 168

20. In your revised prospectus, please identify in the footnote to your table the natural persons

who are the beneficial owners of the shares held by Takeda Vaccines, Inc., as applicable.

Financial

FirstNameStatements, page F-1

LastNameRobert Hershberg, M.D., Ph.D.

Comapany

21.

NameHilleVax,

Please Inc.a description of your capital stock and

revise to provide common November and Page 15, 2021 preferred 5 shares, warrants, etc. in the footnotes to your financial statements. FirstName LastName Robert Hershberg, M.D., Ph.D. FirstName LastNameRobert Hershberg, M.D., Ph.D. HilleVax, Inc. Comapany 15, November NameHilleVax, 2021 Inc. November Page 6 15, 2021 Page 6 FirstName LastName General Please provide us with supplemental copies of all written 22. communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications. You may contact Julie Sherman at 202-551-3640 or Terence O'Brien at 202-551-3355 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

disclose the terms of all

Office of Life

Sciences

cc: Cheston J. Larson, Esq.