## September 2, 2021

Mei Mei Hu Chief Executive Officer Vaxxinity, Inc. 1717 Main St, Ste 3388 Dallas, TX 75201

Re: Vaxxinity, Inc.
Draft Registration

Statement on Form S-1

2021

Submitted August 6,

CIK No. 0001851657

Dear Ms. Hu:

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

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

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

comments.

Draft Registration Statement on Form S-1

Market, Industry and Other Data, page iii

1. Your statements that

(i) neither you nor the underwriters have independently verified any third-party information, (ii) data from your internal research has not been verified by any independent source and (iii) investors are cautioned not to place undue reliance on such market and industry data or any other such estimates may imply an inappropriate disclaimer of responsibility with respect to the third party information and internal research. Please either delete these statements or specifically state that you are liable for such information.

Mei Mei Hu FirstName Vaxxinity

Vaxxinity, LastNameMei Mei Hu

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Prospectus Summary, page 1

2. Please balance the disclosure in the Summary by addressing your dependence on

intellectual property rights licensed from UBIA, your intent to enter into a license

agreement with UBIA pursuant to which UBIA would commercialize UB-612 in Taiwan

should the EUA be approved while you would receive royalty payments, and the

difficulties in manufacturing peptide-based medicines. Please revise your disclosure here and in the Business section to provide appropriate context for various conclusions and predictions as to the performance of your product candidates and revise and/or remove any statements that imply safety or efficacy as safety and efficacy determinations are solely within the authority of the FDA or similar foreign regulators. For example, we note statements that one or more of your product candidates can "safely break immune tolerance and target self-antigens," have safety profiles "at least comparable to the competing mAb or small molecule alternative for the relevant disease," penetrate the BBB at a higher rate than mAb, generate antibodies that bind to the S1-RBD protein and neutralize SARS-CoV-2, "have broken immune tolerance against selfantigens consistently, safely and at therapeutically meaningful levels," "have stimulated the development of antibodies against the desired target in clinical trial subjects (including the elderly) to develop antibodies against the desired target at relevant doses," "help achieve a relatively long duration of action, as B-cells continue to produce antibodies following a dose," "could offer similar efficacy as mAbs at a meaningfully lower cost and improved administrative convenience to patients, thereby potentially allowing for access to broader patient populations versus mAbs, and greater efficacy than small molecules," "may have the potential to help ease the global COVID-19 pandemic," "have the potential to be as or more effective than comparable mAb and small molecule treatments," and that you "believe the concentrations of antibodies elicited by [y]our neurodegenerative disease product candidates may potentially prove relevant for clinical success." Please revise this disclosure and similar statements throughout your prospectus to remove any suggestion that there is an expectation that your product candidates will be safe or effective or will have improved performance over approved therapies. You may provide a summary of the data that you used to draw these conclusions but not the conclusions or predictions, and such discussion is more appropriate in the Business section where full and proper context can be provided. We note several comparisons to certain approved therapies in the Summary and in the Business section, including the chart on pages 3 and 109 comparing the attributes of your product candidates to mAbs and small molecule therapeutics. If you have not conducted head-to-head trials, please revise your disclosure to clearly state this fact and disclose why you believe these comparisons are appropriate. If you provide disclosure regarding results from other trials, expand your disclosure to provide the other information regarding these trials that would help an investor make a meaningful comparison and understand the supporting trials and any limitations and qualifications associated with such trials (e.g., number of patients and whether any patients dropped out of the trial or were otherwise Mei Mei Hu FirstName Vaxxinity, LastNameMei Mei Hu Inc. Comapany 2, NameVaxxinity, September Inc. 2021 September Page 3 2, 2021 Page 3 FirstName LastName excluded and the reasons, patient population, dosage, how the baseline was measured in
each study, the phase of the trial, serious adverse events, etc.).
Our Solution, page 2

5. Please revise to eliminate your conclusions as to the effectiveness and safety of your

product candidates in the chart on pages 3 and 109 as findings of safety and efficacy are

solely within the authority of the FDA and are assessed throughout all clinical trial phases.
Our Pineline page 3

Our Pipeline, page 3

6. Please clarify what you mean by "IND" in the column header. It is not clear what this

column is meant to reflect since you have UB-313, which has initiated IND-enabling

studies, and PCSK9, which has yet to initiate IND-enabling studies according to your  $\,$ 

disclosure, with activity in this column.

Our Strategy, page 5

advance" your chronic disease pipeline. Please revise this disclosure to remove any

implication that you will be successful in commercializing your product candidates in a

rapid or accelerated manner as such statements are speculative. Risks Related to Our Class A Common Stock and This Offering, page 65

8. Please expand your risk factor discussion to discuss that future issuances of your Class  $\ensuremath{\mathsf{B}}$ 

 $\,$  common stock as well as mandatory and optional conversions of your Class B common

stock may be dilutive to holders of your Class A common stock. Use of Proceeds, page 77  $\,$ 

9. Please revise your disclosure to indicate how far the proceeds from the offering will allow

you to proceed with continued development of each program referenced. Management's Discussion and Analysis of Financial Condition and Results of Operations

Research and Development Expenses, page 92

10. We note the statement on page 89 that you track direct research and development

expenses on a program-by-program basis. Please revise the filing to provide more

quantified detail for your research and development expenses for each period presented,

including but not limited to by product candidate as well as by the type or nature of

expense.

Determination of the Fair Value of Common Stock, page 100

11. 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

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

up to the initial public offering and the estimated offering price.

This information will help facilitate our review of your accounting for equity issuances

including stock compensation. Please discuss with the staff how to submit your

response.

Business, page 103

12. With respect to the discussion of the clinical trials for each of your product candidates in

they were and how many subjects experienced them.

Our Strategy, page 106

EUA be

13. We note that several steps of your strategy depend on approval of the EUA for UB-612 in

Taiwan. Please make it clear in this section that there is no guarantee that the EUA for

 $$\operatorname{UB-612}$  will be approved and your intent to enter into a license agreement with  $\operatorname{UBIA}$ 

pursuant to which UBIA would commercialize UB-612 in Taiwan should the

approved while you would receive royalty payments.

Development Plans for UB-311, page 123

14. We note your disclosure that you expect that together, the Phase 2b trial and the Phase 3  $\,$ 

program, if successful, will provide sufficient data to enable filing a BLA with the FDA.

Please revise to state that there is no guarantee that you will not have to do additional  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

trials or studies prior to a BLA submission.

Our Product Candidate: UB-312, page 124

15. We note your statement here regarding your belief that the concentrations of antibodies

elicited by your neurodegenerative disease product candidates may potentially prove

relevant for clinical success, your statement on page 128 that a capsaicin-induced dermal

blood flow model in mice has demonstrated strong translational value into clinical  $\ensuremath{\mathsf{N}}$ 

efficacy, and your statement on page 134 that the ratio of titers seen in trials of UB-612 is  $\,$ 

similar to that of other approved and clinical-stage vaccines that have shown efficacy in  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

your product candidates will demonstrate clinical efficacy. Please revise these statements  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

accordingly.

UBIA License Agreement, page 140

16. Please revise the reference to "mid-double-digit" royalties to a royalty range within ten

percentage points (for example, between twenty and thirty percent). Aurobindo License Agreement, page 141

17. Please revise to disclose a range for the tiered royalties no greater than ten percent.

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Vaxxinity, LastNameMei Mei Hu

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Principal Stockholders, page 171

18. Please revise your disclosure to identify the natural person or persons who have voting

and investment control of the shares held by United Biomedical, Inc. and the entities  $\,$ 

affiliated with Prime Movers Lab Fund I LP.

Common Stock, page 173

19. Please disclose the percentage of outstanding shares that Class B shareholders must

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approval.

20. We note your disclosure that each share of Class B common stock will automatically

convert into one share of Class A common stock upon any transfer, whether or not for

value and whether voluntary or involuntary or by operation of law, except for certain  $% \left( 1\right) =\left( 1\right) +\left( 1$ 

transfers described in your charter, including, without limitation, certain transfers for tax

and estate planning purposes. Please clarify the scope of this exception. Explain the

circumstances under which these transfers may occur without automatic conversion of the

shares and the parties to whom the shares may be transferred, including whether shares

may be transferred upon death or total disability of a Class B holder without conversion.

Description of Capital Stock, page 173

We note that you refer shareholders to, in part, the relevant provisions of the Delaware

General Corporation Law. It is not appropriate to qualify your disclosure by reference to

information that is not included in the filing or filed as an exhibit. Please revise

accordingly.

Note 13 - Common stock, page F-26

We note from your combined consolidated statements of convertible preferred stock and

stockholders' deficit on page F-5 that you issued 51,350,191 shares of common stock

during the year ended December 31, 2020. Please disclose the significant terms of the

transaction(s) of the common stock issuance.

General

23. 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(d) of the Securities Act, whether or

not they retain copies of the communications.

Mei Mei Hu

Vaxxinity, Inc.

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You may contact Eric Atallah at 202-551-3663 or Kevin Kuhar at 202-551-3662 if vou

have questions regarding comments on the financial statements and related matters. Please

contact Ada D. Sarmento at 202-551-3798 or Jeffrey Gabor at 202-551-2544 with any other

questions.

Sincerely,

FirstName LastNameMei Mei Hu

Division of Corporation

Finance Comapany NameVaxxinity, Inc.

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Joseph D. Zavaglia, Esq.

FirstName LastName

Office of Life Sciences