



DIVISION OF  
CORPORATION FINANCE

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

June 4, 2020

Axel Bolte  
President and Chief Executive Officer  
Inozyme Pharma, Inc.  
321 Summer Street  
Suite 400  
Boston, Massachusetts 02210

**Re: Inozyme Pharma, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted May 8, 2020**  
**CIK No. 0001693011**

Dear Mr. Bolte:

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 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.

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.

Registration Statement on Form S-1

Company Overview, page 1

1. We note your disclosure here and throughout that you are pursuing the development of potentially "first-in-class" therapeutics. That term may suggest that your product candidates are effective, likely to be approved and favorable as compared to competitive products and product candidates. Given the status of development, it is premature for you to make such statements or implications at this time. Accordingly, please revise to remove any disclosure in your registration statement regarding your therapeutics as being potentially "first-in-class."

Pathological Diseases of Abnormal Mineralization, page 1

2. We note that your disclosure in the third paragraph on page 3 indicates the number of patients with the enzyme deficiencies you are targeting are based on worldwide estimates. Since you currently intend to seek regulatory approval for your products in the United States and Europe, please revise to clarify your market opportunity in those targeted markets or clarify your risks in that regard.

Our Solution: INZ-701, page 2

3. You state at the bottom of page three, "[t]here are currently no approved therapies for calciphylaxis," and address it as "a particularly attractive area for drug development for abnormal mineralization," and include it in your pyramid graphic as a place for significant expansion of your product candidates (visually, as one of the widest portions of the graphic, even if the calculations underlying the potential market do not meet the visual depiction). On pages 30 and 131, however, you disclose you have competition in the calciphylaxis area, stating "SNF472, a calcification inhibitor, is currently in Phase 3 clinical development for calciphylaxis by Sanifit, and Inositec has product candidates in preclinical development for calcification inhibitors." Revise your summary to balance your emphasis on this potential indication against the realities you describe elsewhere.
4. In the pyramid graphic and pipeline table on pages 4, 110, and 112, you include INZ-701 in different forms for treating ENPP1 deficiency in both adults and children and ABCC6 deficiency, and also for potential applications still in discovery stage. Please revise the pyramid graphic and pipeline table to include only those programs that are material to the company. If you believe that every program listed is material, please provide us with an analysis explaining your belief. In your response, address the import of including the pyramid graphic, which appears to only convey that you wish to grow your business, and repeats information included in your summary while emphasizing potential applications for which you are still in the discovery phase. In addition, you do not separately address the pediatric and adult applications of IND-701 for ENPP1 deficiency when discussing your IND applications in your use of proceeds or when you address your strategy for advancing your products. If these are not distinct products revise the table to make this clear. Finally, revise the pipeline table to provide some indication of the timing of applications for IND or CTA in order to provide a more complete view of the stage of your potential products relative to the entire approval process.
5. Revise the summary to include your intent to conduct the clinical trials for your products outside the U.S., and to highlight the associated risks, as noted on page 26.
6. We note your disclosure in the second to last paragraph of this section that you plan to engage with the regulatory authorities in the United States, Europe and other jurisdictions to determine appropriate primary efficacy endpoints and other requirements for potential marketing approval. Please balance this disclosure by disclosing that you may propose new or novel endpoints and may be unable to establish clinical endpoints that the

applicable regulatory authorities would consider clinically meaningful.

Pipeline, page 4

7. Above the pipeline table and elsewhere, you address your "pipeline and programs, including INZ-701." The table and elsewhere only features INZ-701. If you do not have other material product candidates to disclose, revise your disclosure throughout to clarify.
8. Revise your summary to clarify that you are licensing your technology from Yale and that it is contingent on your continued relationship with Yale and Dr. Braddock, as disclosed on page 132 and elsewhere in the prospectus.

Our Team, page 5

9. We note your disclosure here and on page 110 regarding the "leading" investors providing your funding, and on page 111 related to the "leading" clinicians with whom you work. Revise to clarify what makes the investors and clinicians "leading" or delete these references.

Risk Factors, page 12

10. We note the risk factor related to orphan drug designation on pages 57-58. In the heading, you address orphan drug designation by both the FDA and EMA; however, in the body of the risk factor, you do not address risks related to EMA orphan drug designation. Please revise to address those risks.

Use of Proceeds, page 81

11. You list your use of proceeds as: (1) "for the completion of our IND submission and conduct of our Phase 1/2 clinical trial of INZ-701 for ENPP1 deficiency;" and (2) "for the completion of our CTA submission and conduct of our Phase 1/2 clinical trial of INZ-701 for ABCC6 deficiency," as well as additional uses. We note these activities addressed on page 129. Please disclose the significance of receiving orphan drug designation from the CTA for the treatment of ENPP1 deficiency (as stated on page 108) if you do not plan to pursue those clinical trials in connection with your CTA submission and clarify whether you will use a material portion of the proceeds to amend and resubmit INZ-701 to the FDA for orphan drug designation for the treatment of ABCC6 deficiency. In addition, we note the risk factor disclosure that you may seek Rare Pediatric Disease Designation for either of your product candidates. Please disclose whether you intend to use any of the proceeds to seek this designation. We note that designation would need to be achieved before September 30, 2020, as disclosed on page 58. We note it appears that application would likely need to be made by July 31, 2020 to potentially obtain a response by September 30, per the FDA's website. If you have no current plans, advise whether this risk factor disclosure is relevant, or may be relevant by the time this registration statement becomes effective.

Management's Discussion and Analysis  
License and Sponsored Research Agreements, page 91

12. Here and on page 132, revise the disclosure regarding the "double-digit" percentages you must pay to Yale on certain types of income you receive from sublicensees to disclose a range within ten percentage points.

Business  
INZ-701: Preclinical Results and Data, page 121

13. On page 125, you state, "Treatment with 5 mg/kg of INZ-701 completely prevented calcification in the heart and aorta." If you tested the same number of mice at each dosage level, there appears to be a subject that was dosed at 5mg/kg missing from the graphic. Please revise to clarify. We also note that you do not appear to disclose a p-value associated with the results shown in the graphic. If the results shown could be due to chance, please revise to make that clear.

Consulting Agreement with Demetrios Braddock, page 182

14. As your ability to maintain your agreement with Dr. Braddock appears to be the key to your Yale licensing agreement, provide the consulting agreement with Dr. Braddock as an exhibit in accordance with Regulation S-K Item 601(b)(10)(ii)(B).

Exclusive Forum Selection, page 190

15. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. If the provision applies to Securities Act claims, please state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please ensure that the exclusive forum provision in the governing documents states this clearly.

General

16. 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.

Axel Bolte  
Inozyme Pharma, Inc.  
June 4, 2020  
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You may contact Gary Newberry at (202) 551-3761 or Jeanne Baker at (202) 551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Tim Buchmiller at (202) 551-3635 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Brian A. Johnson, Esq.