

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

May 8, 2024

Martin Babler
President and Chief Executive Officer
Alumis Inc.
280 East Grand Avenue
South San Francisco, CA 94080

Re: Alumis Inc.

Draft Registration Statement on Form S-1 Submitted April 11, 2024 CIK No. 0001847367

Dear Martin Babler:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 Submitted April 11, 2024

#### Cover Page

 Disclose whether your offering is contingent upon final approval of your Nasdaq Global Market listing on your cover page. Please ensure the disclosure is consistent with your underwriting agreement.

# Prospectus Summary

#### Overview, page 1

2. We note your disclosure on page 29 that you acquired ESK-001 via a stock purchase of FronThera U.S. Holdings, Inc. and its wholly-owned subsidiary, FronThera U.S. Pharmaceuticals LLC, and your disclosure on page 88 that, under the stock purchase agreement, you are obligated to pay contingent consideration of up to \$120.0 million based on the achievement of specified clinical and commercialization milestones. If any of the material product candidates you are developing were acquired in this transaction,

please include appropriate disclosure in your prospectus summary and include disclosure regarding these potential milestone payments. Please also tell us why it would not be appropriate to file this stock purchase agreement as an exhibit to the registration statement. Refer to Item 601(b)(10) of Regulation S-K.

#### Our Pipeline, page 2

- 3. We note your statements in the first paragraph of this section and on pages 4, 97, and 98 regarding the opportunity to develop a "best-in-class" profile for ESK-001. Given the development stage of your programs and length of the drug approval process, it appears to be premature to speculate or imply that ESK-001 will be approved or become best-in-class for any indication at this time. Please revise these statements and any similar statements throughout.
- 4. We note your statements that your clinical trial "data demonstrated that ESK-001's ability to maximally inhibit TYK2 translates to the achievement of high rates of response...in patients, with response rates in the range observed with existing biologic therapies" and that your Phase 2 STRIDE trial "met its primary endpoint, the proportion of patients achieving a 75% improvement...at week 12 compared to placebo." To balance the disclosure in your prospectus summary, please disclose any adverse events observed in the Phase 2 STRIDE trial or include a cross reference to the relevant disclosure in the "Business" section. In this regard, we note your disclosure of adverse events in your Phase 2 STRIDE trial and in your open label extension on pages 107, 108, and 110. Please also clarify what you mean by "maximally inhibit TYK2" since from the figure on page 111 it does not appear that TYK2 is completely inhibited at the dose ranges shown in that figure.
- 5. We note your disclosure on pages 3 and 96 that "A-005 has demonstrated protective effects in multiple *in vivo* disease models of neuroinflammation." Please briefly describe the preclinical studies and the results thereof that led to this conclusion. If the experimental autoimmune encephalitis (EAE) model is the model that supports this disclosure, please make that clear.
- 6. We note your disclosure on page 114 that you are evaluating ESK-001 in an ongoing Phase 2a clinical trial in patients with Uveitis. Since it appears that the related arrow in your pipeline table is half-way through the Phase 2 portion of the row, please tell us if it would be appropriate to shorten the arrow in that row to reflect that you are still in Phase 2a of the trial. Also clarify if you anticipate conducting a Phase 2b trial prior to proceeding to a Phase 3 trial for this indication.
- 7. We note your disclosure on page 116 that you intend to pursue MS as your initial indication for A-005. If you have not definitively selected MS as your targeted indication for A-005, please tell us why it is appropriate to include a row for A-005 in your pipeline table here and on page 97 or revise your disclosure as appropriate.

# Our Strategy, page 4

8. We note your description here and on page 98 that A-005 is a "potential first-in-class allosteric TYK2 inhibitor designed to penetrate the CNS to treat neuroinflammation." Please remove the references to "first-in-class" or explain why you believe A-005 is a "potential first-in-class" allosteric TYK2 inhibitor, including, for example, whether you are aware of any competing product candidates that are further along in the development process.

# Use of Proceeds, page 73

- 9. We note that you intend to use the proceeds from this offering for multiple purposes, including "to fund clinical development and related studies for product candidates as well as [y]our activities in preparation for such clinical development." We also note your disclosure that the proceeds "will not be sufficient for [you] to fund [y]our programs through regulatory approval and commercialization" and that you "will need to raise substantial additional capital in order to do so." Please revise your disclosures in this section to:
  - identify how you intend to allocate the proceeds among the various intended purposes;
  - clarify which products or programs you currently intend to fund with the proceeds from this offering;
  - disclose how far into the development process you anticipate such proceeds will enable you to reach; and
  - state the anticipated amount of other funds, if any, that may be necessary to accomplish the specific purposes for which the proceeds are to be obtained.

# Management's Discussion and Analysis of Financial Condition and Results of Operations Sources of Liquidity, page 86

10. We note your disclosure in the third paragraph that, prior to the occurrence of certain timelines or events, you have an obligation to sell additional shares of your Series C redeemable convertible preferred stock. Please revise your disclosure to clarify whether the described obligations are eliminated after the earlier to occur of the listed timelines or events or update your disclosure when appropriate to indicate how these obligations have been satisfied.

# <u>Critical Accounting Policies and Significant Judgments and Estimates</u> <u>Stock Compensation Expense, page 90</u>

11. Once you have an estimated offering price range, please explain to us the reasons for any differences between recent valuations of your common stock leading up to the planned offering and the midpoint of your estimated offering price range. This information will facilitate our review of your accounting for stock compensation.

#### **Business**

# Our Precision Approach and Capabilities, page 98

- 12. We note your references to "[y]our precision data analytics platform" throughout the prospectus. We further note your reference on page 98 to benefitting from Foresite Labs' data platform and your establishment of "a precision data analytics platform" with Foresite Labs' capabilities as a foundation. Please clarify whether you own or in-license the precision data analytics platform discussed throughout the prospectus, and if inlicensed, please briefly describe the material terms of the license agreement or other arrangement.
- 13. Please explain the basis for your belief "that the application of insights from [y]our internal efforts, combined with [y]our Foresite Labs collaboration, may ultimately bring forth the most effective, paradigm-shifting medications by optimizing [certain] design elements." In addition, explain what you mean by "paradigm-shifting." To the extent material, please also address, in the risk factors section, the potential risks that could arise in the event your collaboration with Foresite is terminated.
- 14. At the bottom of page 99, you describe the figure at the top of page 100 as an illustration of the indications that you "are pursuing" for your TYK2 franchise. Please revise this sentence to clarify the indications you are currently pursuing and which ones are potential additional indications of interest.

#### Right Target, page 99

15. Please clarify if the proprietary genetic database you refer to was developed by you or inlicensed or acquired. Please also indicate the basis for your belief that drugs with indications supported by human genetics have twice the likelihood of success in Phase 2 and Phase 3 clinical development.

# Right Molecule, page 99

16. Please clarify if you designed ESK-001 and A-005 using the methods described in the first bullet point of this section.

#### Role of TYK2 in Immunology, page 101

17. In the second bullet point at the top of page 3, you state you design your molecules to achieve maximal target engagement and a "safe pharmacological profile." In the last sentence on page 101, you state, "this TYK2 variant does not appear to significantly increase susceptibility to serious infections, suggesting that TYK2 inhibition may be associated with an optimal balance between efficacy and safety." We note similar disclosures on page 111 that your "STRIDE Phase 2 clinical trial and open label extension trial in PsO demonstrated that ESK-001 at a dose of 40 mg BID was well tolerated and highly efficacious" and on page 117 that "A-005 can effectively inhibit TYK2 microglial responses in primary microglia derived from human induced pluripotent

stem cell...." Please revise your prospectus to remove any statements regarding efficacy or safety determinations as such determinations are solely within the authority of the FDA.

#### Preliminary Results from the Ongoing OLE Trial, page 108

- 18. Please disclose whether the ongoing OLE trial is powered for statistical significance, and if so, disclose the p-values for the preliminary results discussed in this section.
- 19. We note your disclosure on page 110 that there have been five serious adverse events in the OLE trial, including two that you have assessed to be possibly related to study drug. Similar to your disclosure in the risk factor on page 18, please disclose here the nature of these serious adverse events.

#### Proposed Phase 3 Clinical Trials of ESK-001 in PsO, page 112

20. Please disclose the regulatory jurisdictions where you intend to conduct your proposed Phase 3 clinical trials for ESK-001 in PsO. We also note your disclosure that ESK-001 has the potential to be a best-in-class TYK2 inhibitor and that, if approved, ESK-001 would compete with several currently approved or late-stage oral clinical therapeutics, including Sotyktu. Given that disclosure, please clarify your reasons for using Otezla as a comparator and clarify how you would substantiate your intended best-in-class claims with results from these trials.

# Ongoing Phase 2b LUMUS trial of ESK-001 in SLE, page 113

21. Please disclose the regulatory jurisdictions where you are conducting your Phase 2b clinical trial. We also note your disclosure that this trial is designed to potentially serve as the first of two pivotal trials. Please clarify if this means that you might be able to have the Phase 2b trial serve as the basis for seeking regulatory approval or if you would need to conduct Phase 3 trials.

#### A-005: Our CNS Penetrant Allosteric TYK2 Inhibitor, page 116

22. We note your disclosure here and on page 119 that you have initiated a "multi-cohort investigation to assess...orally-administered A-005." Please clarify whether this is a different study than the Phase 1 study of A-005 that you reference on pages 1, 3, 79, 95, and 96. In addition, describe the clinical protocol for the Phase 1 study and, if different, for this investigation, including any primary and secondary endpoints.

#### A-005 Preclinical Validation, page 117

23. Please provide some additional narrative explaining the data presented in the figures on pages 117 and at the top of page 118.

# First in human study, page 119

24. Please disclose the regulatory jurisdiction where this study is being conducted.

#### Foresite Labs Collaboration, page 120

25. We note your disclosure regarding your Services Agreement with Foresite Labs, a related party. Please tell us what consideration you gave to filing this Services Agreement as an exhibit to your registration statement. Refer to Item 601(b)(10) of Regulation S-K.

# Government Regulation, page 124

26. We note from page 123 that you "intend to commercialize [y]our product candidates, if approved, in key markets in the United States, the European Union, and APAC...." We also note from page 112 that you have received and incorporated feedback from the FDA and the CHMP in Europe in your proposed Phase 3 program in PsO and that you have requested regulatory feedback from the PMDA in Japan. However, the government regulation discussion in this section only substantively addresses the United States. Please tell us what consideration you gave to also addressing applicable government regulations regarding Europe and Japan.

#### Management

# Composition of Our Board of Directors, page 137

27. We note your disclosure that you have one vacancy on your board of directors and that the vacancy is a position that, under the terms of a voting agreement you entered into with certain of your stockholders, is to be filled, upon mutual agreement of your board of directors, by a person who is not otherwise your employee or affiliate. We further note your disclosure that the voting agreement will terminate upon closing of the offering. Please revise your disclosure to clarify your intent with respect to the vacancy, including whether you intend to fill the vacancy pursuant to the terms of the voting agreement prior to its termination or otherwise pursuant to the terms of your constituent documents after closing of this offering.

# <u>Certain Relationships and Related Person Transactions</u> <u>Series B and Series B-1 Redeemable Convertible Preferred Stock Financing, page 158</u>

28. In footnote 3 to the table, you state, "Immediately prior to the closing of this offering, all shares of our redeemable convertible preferred stock held by entities affiliated with BBA will convert into...shares of [y]our common stock and...shares of [y]our non-voting common stock." You do not include a similar statement in footnotes 2 and 4 to the table. Please revise your footnote disclosure to disclose what will happen to the redeemable convertible preferred stock held by the other entities in the table in connection with the closing of this offering. In this regard, we note your disclosure on page 166 that "[a]ll...outstanding shares of redeemable convertible preferred stock will be converted into

an aggregate of...shares of common stock and...shares of non-voting common stock immediately prior to the closing of this offering." This comment also applies to the footnotes on pages 159, 160, and 163.

# Principal Stockholders, page 162

- 29. In the fourth paragraph, you state that the percentage ownership of a person is calculated by dividing the number of shares such person holds by a sum that includes the number of shares of non-voting common stock that the person has the right to convert to common stock within 60 days. Please revise the footnotes to the table, including footnote 10, to clarify the number of shares of non-voting common stock, if any, held by each listed stockholder.
- 30. In footnotes 4 and 5 to the table, please clarify whether the trustees have sole or shared voting and dispositive power over the applicable shares referenced therein.

#### Common Stock and Non-Voting Common Stock, page 165

- 31. We note that your amended and restated certificate of incorporation will authorize two classes of common stock. Please describe the differences, if any, in the information that the holders of each class will receive, and the timing of receiving such information, as compared to the information provided to holders of the other class.
- 32. We note that holders of your non-voting common stock will have the right to convert each share of non-voting common stock into one share of common stock at the respective holder's election, subject to certain restrictions. Please also disclose whether there are any automatic or mandatory conversion provisions associated with the non-voting common stock.

#### Voting Rights, page 165

33. You state that your non-voting common stock is not entitled to any votes per share, except as required by law, and you identify some instances in which holders of non-voting common stock would have a right to vote. Please revise your disclosure to clarify, in instances where non-voting common stockholders have a right to vote, the number of votes to which each share of non-voting common stock is entitled and whether the non-voting common stockholders would vote separately or together as a single class with the common stockholders. For the matters that require the approval of the non-voting common stock described in clause (iii)(A) and (B), please include appropriate risk factor disclosure, and revise here to describe the Fundamental Transactions that would require the approval of the holders of the non-voting common stock.

#### No Preemptive or Similar Rights, page 166

34. You state that shares of your common stock and non-voting common stock are not subject to conversion provisions. Please revise this statement to clarify that the non-voting

common stock is subject to conversion provisions, as discussed on page 165.

# **Underwriting**

# Directed Share Program, page 178

- 35. We note your disclosure here and in other parts of the prospectus regarding your directed share program. Please revise your prospectus to clarify, where appropriate, including in the risk factors and in the "Principal Stockholders" section, that:
  - your directors, officers, employees, business associates, and related persons may participate in this program, resulting in further concentration of beneficial ownership and control than is reflected in the prospectus; and
  - the beneficial ownership and control disclosures presented in the prospectus assume that no shares of common stock are purchased by your directors, officers, employees, business associates, and related persons pursuant to the directed share program.

In addition, please expand your disclosure to address the process that prospective participants will follow to participate in the program, the manner in which you will communicate with prospective participants about the program, when and how you will determine the allocation for the program, whether such allocation will change depending on the interest level of potential participants, and any other material features of the program.

#### Notes to Consolidated Financial Statements

#### 6. Related Party Transactions, page F-18

36. Revise to disclose the relationship with Foresite Labs, LLC and related entities, detailing any other transactions with these parties.

#### 7. Commitments and Contingencies

# Operating Leases, page F-19

37. Please provide an accounting analysis for the operating leases that constituted ROU assets of \$12.7 million and associated liabilities of \$32.6 million on December 31, 2023 that includes an explanation for the difference between these amounts. Refer us to the technical guidance upon which you relied and revise your disclosure accordingly.

#### FronThera Contingent Consideration, page F-20

38. Please describe and quantify terms governing your acquisition of FronThera and accounting treatment for this asset acquisition. Refer us to the technical guidance upon which you relied and revise your disclosure accordingly.

#### Item 16. Exhibits and Financial Statement Schedules, page II-3

39. You list a Registration Rights Agreement between you and certain of your stockholders as Exhibit 4.3. Please tell us whether this registration rights agreement includes both the registration rights agreement you intend to enter into with Baker Brothers prior to closing,

as discussed on page 161, and the registration rights agreement you discuss on page 167 under "Registration Rights." If it is not, please confirm that you will file copies of both registration rights agreements as exhibits to the registration statement.

#### General

40. 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.

Please contact Franklin Wyman at 202-551-3660 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Dickerson at 202-551-8013 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Dave Peinsipp, Esq.