

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

December 11, 2024

Lei Huang Chief Executive Officer Denali Capital Acquisition Corp. 437 Madison Avenue, 27th Floor New York, NY 10022

Jaisim Shah
Chief Executive Officer and President
Semnur Pharmaceuticals, Inc.
960 San Antonio Road
Palo Alto, CA 94303

Re: Denali Capital Acquisition Corp. Registration Statement on Form S-4 Filed November 6, 2024 File No. 333-283019

Dear Lei Huang and Jaisim Shah:

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

Please respond to this letter by amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments.

Registration Statement on Form S-4 filed November 6, 2024

Cover Page

1. Please revise the prospectus cover page to include disclosure highlighting the number and each type of security being registered, including disclosure as to how you arrived at the number of securities being registered. In this regard, we note from the header on the prospectus cover page that you are registering 262,684,337 shares of common stock, 524,622 units, 6,000,000 shares of Series A Preferred Stock, and 8,760,000 warrants of New Semnur.

- 2. On page i, you state that holders of Denali Class A Ordinary Shares will be asked to approve and adopt the Merger Agreement. With reference to the disclosure on page 46, please revise your disclosure to clarify that holders of Denali Class A Ordinary Shares and holders of Denali Class B Ordinary Shares, voting together as a single class, will be asked to approve and adopt the Merger Agreement, or otherwise advise.
- 3. Please revise the sponsor compensation disclosure on pages iii and iv to also include any compensation received or to be received by the directors and officers of Denali, as well as the Denali underwriters. Refer to Item 1604(a)(3) of Regulation S-K. Please make similar revisions as appropriate in the sponsor compensation disclosure on pages 42-43 and 86.
- 4. We note your disclosure on page ii and throughout the prospectus that, from and after the Effective Time, and for so long as Scilex beneficially owns any shares of New Semnur Series A Preferred Stock, Scilex will have the right, but not the obligation, to designate each director to be nominated, elected or appointed to the New Semnur Board. However, we further note your disclosure elsewhere in the prospectus that, upon and following consummation of your initial business combination, the Sponsor will be entitled to nominate three individuals for appointment to the board of directors as long as the Sponsor holds any securities covered by an April 6, 2022 registration rights agreement. Please revise your disclosures throughout the prospectus as appropriate to clarify who will have the right to designate and/or nominate directors to the New Semnur Board.
- 5. Please revise the table on page iii, and elsewhere as applicable, to clarify the post-combination holdings of Scilex Holding Company. In this regard, it should be clear that Scilex will own nearly all of Semnur's equity securities following the combination and that this stake will not be held by multiple stockholders.
- 6. We note your disclosure on page viii that Denali intends to list the New Semnur Common Stock and warrants on the Nasdaq Capital Market upon completion of the Business Combination. Please disclose here whether completion of the Business Combination is contingent on this listing approval.
- 7. On page viii, you disclose that the Denali Board determined that it is advisable to consummate the Business Combination. Please also disclose, if true, that the Board determined the Business Combination was in the best interests of Denali and its shareholders. In this regard, we note a similar statement on pages 47 and 175. Refer to Item 1604(a)(1) and Item 1606(a) of Regulation S-K.
- 8. Please revise the prospectus cover page to include the information required by Item 1604(a)(2) of Regulation S-K. Please make similar revisions to the summary of the proxy statement in accordance with Item 1604(b)(5).

About this Proxy Statement/Prospectus, page viii

9. You state that the prospectus is with respect to the Denali Class A Ordinary Shares to be issued to Semnur's stockholders under the Merger Agreement. However, the prospectus cover page refers to shares of common stock, units, shares of Series A Preferred Stock, and warrants. Please revise your disclosures as appropriate.

Questions and Answers about the Business Combination and the Meeting Questions and Answers about the Business Combination, page 7

- 10. Please revise the disclosure on pages 7-8 to include a new Q&A that explains the reason(s) why Scilex is conducting the Business Combination and related transactions, as well as its plans for Semnur in the short term and the long term. For instance, please explain here, and in the Background section, why Scilex determined to retain 96% or greater of Semnur's equity as opposed to spining-off all of the Semnur equity. With reference to the potential 10% stock dividend referenced on page 13 and the Oramed debt, revise to discuss whether Scilex plans to distribute additional Semnur stock to its shareholders and, as applicable, the factors that will determine the timing and size of such distributions. Also explain why Scilex is opting to merge Semnur with a SPAC given the amount of proceeds currently in the Trust Account and the prospects for additional redemptions.
- 11. With reference to your disclosures on pages 110, 298 and 304, please add a new Q&A that discusses Scilex's continued operational and voting control over Semnur following the Business Combination as well as Semnur's reliance on funding and services provided by Scilex. Highlight the risk that the interests of Scilex and certain officers and directors who jointly serve as officers/directors at Scilex and Semnur may not be aligned with those of other Semnur stockholders and this could lead to actions that may not be in the best interests of Semnur stockholders.

What equity stake will current Denali shareholders and Semnur stockholders hold..., page 10

12. We note your disclosure in the second paragraph that the ownership percentage with respect to New Semnur after the closing of the Business Combination does not take into account the potential dilutive effect of several different securities, including the Public Warrants, the Denali Class A Ordinary Shares and Public Warrants underlying the Public Units, and the Denali Private Placement Shares and Denali Private Placement Warrants underlying the Denali Private Placement Units. Please tell us why you have excluded these from the ownership percentage post-closing, particularly the Denali Class A Ordinary Shares underlying the Public Units and the Denali Private Placement Shares underlying the Denali Private Placement Units.

Did the Denali Board obtain a third-party valuation or fairness opinion in determining whether to proceed with the Business Combination?, page 14

13. We note the disclosure here and on the cover page highlighting the \$2.5 billion valuation of Semnur. To the extent that you highlight this valuation, please revise to provide balance and context by also disclosing the current market capitalization for Semnur's parent company, Scilex Holdings.

<u>Summary of the Proxy Statement</u> <u>Semnur Pharmaceuticals, Inc., page 29</u>

14. In the second paragraph, you state that SP-102 has been granted fast track designation by the FDA. We note similar disclosure on pages 262 and 263. When discussing the fast track designation, please also disclose that such designation may not lead to a faster development or regulatory review process and that it does not increase the

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likelihood that SP-102 will receive marketing approval.

Summary of the Proxy Statement

The Meeting

Record Date; Outstanding Shares; Shareholders Entitled to Vote, page 46

15. You state that each holder of Denali Ordinary Shares is entitled to one vote per share on each proposal. However, on page 355, you state that, in a vote to continue Denali in a jurisdiction outside the Cayman Islands, holders of the Denali Class B Ordinary Shares will have ten votes for every Denali Class B Ordinary Share. Please revise your disclosures to reconcile this apparent inconsistency with respect to the Domestication Proposal.

<u>Proposal 1 - The Business Combination Proposal</u> <u>Background of the Business Combination, page 154</u>

- 16. Please revise the Background section so that it also presents similar information from Scilex's perspective.
- 17. We note that you previously received shareholder approval for a different proposed business combination and subsequently terminated the related merger agreement shortly before entering into the merger agreement for the now proposed Business Combination. Please briefly describe the reasons for the termination of the prior merger agreement and clarify when you first began discussions with Semnur. In this regard, we note you disclose that Henry Ji, Ph.D., the Executive Chairperson of Semnur, met your Chief Executive Officer at your principal executive offices on May 30, 2024 to discuss a potential business combination between Semnur and Denali. However, it is unclear how the parties were introduced and what prompted this meeting.

Opinion of CB Capital, page 160

- 18. Disclose the instructions received by the financial advisor from DECA or the Sponsor, including any limitations imposed by DECA or the Sponsor on the scope of the activities conducted by the financial advisor in connection with the financial opinion. Refer to Item 1607(b)(6) of Regulation S-K.
- 19. Please revise to explain the criteria that CB Capital used to identify these companies so that it is clear why these companies were deemed comparable to Semnur and why other companies were not selected. Based on the information provided, we note that all of the companies selected are commercial stage companies. Please explain why CB Capital did not choose one or more pre-commercial stage companies for purposes of its valuation analysis. From your revised disclosure, it should be clear how CB Pharma came to select some of the largest pharmaceutical companies (by revenues, profits and market capitalization) in the world (*e.g.*, Eli Lily, Pfizer, AbbVie, Amgen, etc.) as companies that are comparable to Semnur.
- 20. Please revise to discuss whether Denali's board reviewed the list of comparable companies selected by CB Capital and agreed that these companies are comparable to Semnur.
- 21. We note that the financial opinion filed as Exhibit 99.4 includes language that the

opinion letter is "provided to DECA for its sole use in considering the proposed Transaction" and that the letter "is not to be used for any other purpose" without the prior written consent of the financial advisor. Please remove these statements. Alternatively, disclose the legal basis for DECA's and the financial advisor's belief that shareholders cannot rely on the opinion to bring state law actions, including a description of any state law authorities on such a defense. If no such authority exists, please disclose that this issue will be resolved by a court, resolution of this issue will have no effect on the rights and responsibilities of DECA's board under state law, and the availability or non-availability of these defense has no effect on the rights and responsibilities of either the financial advisor or DECA's board under the federal securities laws.

- 22. We note the disclosure on page 162 that CB Capital assumed that the projections relating to Semnur's asset portfolio were reasonably prepared based on assumptions reflecting the best currently available estimates and good-faith judgments of Denali's management as to the most likely future performance of Semnur's asset portfolio and that Denali's management did not have any information or belief that would make any such projections incomplete or misleading. Please revise where appropriate to disclose whether Denali's management determined that Semnur's base case projections represented the most likely future performance for Semnur.
- 23. Please file the consent of your financial advisor to be named in the registration statement and to the filing of the fairness opinion as an exhibit to the registration statement. Refer to Section 7 of the Securities Act and Securities Act Rule 436.

Certain Semnur Projected Financial Information, page 175

- 24. We note that the Semnur Management Projections were prepared in August 2024 by Semnur's management with respect to Semnur as a standalone company. Please disclose whether or not Semnur has affirmed to Denali that its projections continue to reflect the view of Semnur's management about its future performance and ensure that such disclosure remains updated through the effectiveness of this registration statement. Refer to Item1609(c) of Regulation S-X.
- 25. Given that the Semnur Managment Projections differ from historical operating trends and the extended forecast period, please expand your disclosure to address why the change in trends is appropriate or the assumptions are reasonable. Please also address the following:
 - Explain the assumptions underlying Semnur's expectation that SP-102 will receive regulatory approval in the first half of 2027 and the milestones that will need to be satisfied in order for SP-102 to achieve this timeline. Describe and quantify the nature and timing of additional clinical, regulatory and commercialization activities necessary to successfully launch SP-102. In this regard, we note that Scilex issued a press release on November 2, 2023 announcing that FDA provided guidance regarding preclinical and clinical data needed prior to an NDA filing and that as a result, an open-label multi-center safety and efficacy trial enrolling approximately 700 patients was planned for the first half of 2024. Clarify the status of this trial and whether it is reflected in the Semnur projections.
 - Provide quantification of the significant assumptions underlying Semnur's

revenue projections, including price per unit, annual growth rate and market share penetration, under the base case and best-case scenarios for each year presented. More clearly explain Semnur's assumptions around the current and future competitive landscape and why they do not expect revenues to be materiality impacted by the loss of patent exclusivity in 2036. Reconcile this outlook with the competition disclosure provided on page 277.

- Describe the risk that the expectations of unusually high and sustained future growth may be unrealistic, given the assumptions as to future events, and may have resulted in inflated valuation conclusions.
- Provide quantification of the significant assumptions underlying Semnur's gross profit projections, including cost of sales, future milestone and royalty payments under the August 2013 Shah Assignment Agreement and March 2019 Semnur Merger Agreement, for each period presented.
- To the extent feasible, provide a breakdown of projected operating expenses by major category and identify key factors driving material period-to-period changes in each expense category.
- Confirm that all associated costs have been included in Semnur's financial projections, including any costs to finance additional clinical, regulatory and commercial activities.

Semnur Management Projections - Base Case Projection, page 177

- 26. We refer to page 142 of Scilex Holdings's Form S-4, filed on 10/26/2022, which relates to a prior SPAC merger involving Scilex. We note that Scilex's management in 2021 projected that SP-102 would be commercialized in 2022 and would achieve revenues of \$1.167 billion in its tenth year of commercialization (2031). By contrast, Scilex management's August 2024 projections now reflect SP-102's commercialization in 2027, revenues of \$4.875 billion in 2031, and revenues of \$5.91 billion in SP-102's tenth year of commercialization (2036). With a view to disclosure, please explain the reason(s) for the significant changes to Scilex management's projections for SP-102.
- 27. We note several references here and throughout the proxy statement/prospectus to Syneos Health, which you note on page 177 was party to a consulting agreement with Semnur. Please file the written consent of Syneos Health as an exhibit to the registration statement. Refer to Section 7 of the Securities Act and Securities Act Rule 436.

<u>Proposal 3 - The Charter Approval Proposal</u> <u>Reasons for the Approval of the Charter Approval Proposal, page 209</u>

28. We note that one of the reasons for the Charter Approval Proposal is to provide a greater number of authorized shares of capital stock for Denali to have sufficient shares to issue to the Semnur stockholders in the Business Combination. Please disclose how many additional authorized shares are needed to complete the Business Combination.

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Business of Semnur
Our Company, page 262

29. In the last paragraph on page 262, you state that you completed a pivotal Phase 3 study with final results received in March 2022, which results reflected achievement of primary and secondary endpoints. Please disclose whether you have pursued any additional development of SP-102 since that time and what, if any, next steps you have planned for SP-102. In this regard, we note your disclosure on pages 73 and 99 indicates that FDA staff has disagreed that your Phase 3 CLEAR trial will be sufficient to support a 505(b)(2) NDA submission and issued guidance requiring you to conduct an additional clinical study for the purpose of collecting additional safety data before submitting the NDA. Please revise to discuss in greater detail the disagreement with FDA, including the availability of the 505(b)(2) pathway, the guidance you received, and when you received it. In this regard, we note Scilex's November 2, 2023 press release announced a Positive Type C Meeting with FDA and discussed Scilex's plan to commence an open-label multi-center safety and efficacy trial in the first half of 2024 in which it would seek to enroll approximately 700 patients with moderate-to-severe Lumbosacral Radicular Pain (LRP).

Our Strategy, page 263

- 30. In the last paragraph on page 263, you state that you expect efficacy of SP-102 to last up to approximately 100 days and that you expect SP-102 to have proven safety based on data from your preclinical and clinical trials. Please revise the disclosure, and any similar disclosures located elsewhere in the prospectus, so that you are not stating or implying that the product candidate is safe or effective, or that it will be determined to be safe or effective, as such determinations are solely within the authority of the FDA.
- 31. In the third bullet point on page 264, you state that a principal element of your strategy is to leverage the robust and integrated commercial infrastructure and other functions of your parent company, Scilex, to commercialize your current and future product candidates, if approved. Please revise your disclosure to clarify the potential impact of the Business Combination on this aspect of your strategy, particularly after the conclusion of any transition period. In this regard, we note your disclosure on page 298 that, in connection with the Business Combination, you intend to enter into a transition services agreement with Scilex that would be in place for two years. Please make similar revisions to your sales and marketing disclosure on page 275 as appropriate.

Our Solution, page 267

32. We note your statement in the first full paragraph on page 268 regarding your expected commercial launch of SP-102 in 2027. Please revise your disclosure to clarify that there is no guarantee that you will be able to commence a commercial launch of SP-102 in 2027 or ever, as any such launch would be subject to regulatory approval, which you may not receive. Please make similar revisions throughout the proxy statement/prospectus as appropriate.

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Material Agreements

Shah Assignment Agreement, page 279

33. Please disclose whether your Chief Executive Officer, Jaisim Shah, has any direct or indirect material interest in the Shah Assignment Agreement and, to the extent applicable, provide the information required by Item 404 of Regulation S-K in the section of the proxy statement/prospectus regarding certain relationships and related party transactions. Refer to Item 18(a)(7)(iii) of Form S-4.

Intellectual Property, page 280

34. We note your disclosure that, with respect to SP-102, your patents and patent applications include formulations and methods of treatment. Please clarify whether you own or in-license these patents and patent applications. For example, clarify whether these patents and patent applications are the subject(s) of the Shah Assignment Agreement.

Liquidity and Capital Resources, page 304

35. With reference to the *pro forma* balance sheet information presented on page 314, please discuss expected Semnur's cash position following the merger and include a quantitative discussion of Semnur's funding requirements for the next twelve months. To the extent that Semnur does not have sufficient cash to fund its operations for twelve months and/or there is material uncertainty regarding the costs of the clinical work that may need to be performed during the twelve month period following the merger, please discuss.

Unaudited Pro forma Condensed Combined Financial Information, page 310

- 36. We note your disclosure on page 319 that Scilex will provide certain services to New Semnur to support operations but that you have not provided autonomous entity adjustments in your pro forma financial statements for any such agreements as they have not yet been executed nor are the terms for such agreements specified. Please address the following:
 - Clarify whether you expect the terms of such agreements to be specified prior to the completion of the Business Combination.
 - Clarify at what point you intend to include any related autonomous entity adjustments in your pro forma financial statements.
 - Explain how your current pro forma presentation absent these adjustments complies with Article 11-01(a)(7) of Regulation S-X.

Semnur's Executive Compensation

2023 Compensation Arrangements with Current Executive Officers, page 333

37. We note your statement that Henry Ji, Ph.D. and Jaisim Shah are the only two executive officers who provided services to Semnur during 2023. We further note your statement that, as Semnur is a wholly-owned subsidiary of Scilex and executives of Scilex are required to provide services to Scilex's subsidiaries, neither of these officers received any cash or equity compensation for services rendered to Semnur during 2023. Please tell us how these officers split their time between Semnur and

Scilex and provide us with your legal analysis for not allocating any of the compensation they received from Scilex to the executive compensation disclosure required by Item 402 for Semnur. Refer to Section 217.08 of the Regulation S-K Compliance and Disclosure Interpretations, available on our website. Please provide a similar analysis for Stephen Ma as we note that you anticipate Stephen Ma will serve as New Semnur's Chief Financial Officer following the closing of the Business Combination. Refer to Item 18(a)(7)(ii) of Form S-4.

<u>Directors and Executive Officers of New Semnur after the Business Combination</u> <u>Executive Officers and Directors after the Business Combination, page 339</u>

- 38. We note that you anticipate the executive officers of New Semnur will be Jaisim Shah, Henry Ji, Ph.D., and Stephen Ma. Please clarify whether these officers will also retain their employment with Scilex and, if so, how they will allocate their time between the two entities.
- 39. Please provide the disclosures required by Item 401(f)(1) of Regulation S-K. Refer to Item 18(a)(7)(i) of Form S-4. In this regard, we note the involvement of Jaisim Shah and Dr. Henry Ji with Sorrento Therapeutics, Inc., which commenced voluntary bankruptcy proceedings in 2023. In addition, to the extent such proceedings, or proceedings arising therefrom, could have a material impact on you, the Business Combination, or New Semnur, please include appropriate risk factor disclosure regarding the same.

Semnur Pharmaceuticals, Inc. - Notes to Financial Statements
Note 1. Nature of Operations and Basis of Presentation
Basis of Presentation - Carve-Out Method, page F-60

40. You disclose that the financial statements of Semnur Pharmaceuticals have been prepared on a carve-out basis and extracted from the accounting records of Scilex. We note that Scilex filed a 4.01 Form 8-K/A on November 22, 2024 announcing the dismissal of EY and disclosed a reportable condition pursuant to Item 304(a)(1)(v) of Regulation S-K. Such disclosure indicated that EY advised the Scilex Audit Committee that information had come to EY's attention that if further investigated may materially impact the fairness or reliability of the financial statements issued or to be issued for the second and third quarters, or cause EY to be unwilling to rely on management's representations or be associated with the registrant's financial statements, and at the time of EY's dismissal on November 19, 2024, such investigation was not complete. We further note that the dismissal of EY resulted in a delay in timely filing Scilex's Form 10-O for the quarter ended September 30, 2024, a Nasdaq delisting notice and potential violation of certain debt covenants, including on the Oramed Note to which Semnur is a guarantor. Please explain the impact that this has or will have on the carve-out financial statements of Semnur Pharmaceuticals. Please also explain your consideration of providing appropriate risk factor disclosure.

General

41. Please provide the disclosures required by Item 305 of Regulation S-K for each of Denali and Semnur. Refer to Item 14(j) and Item 17(b)(10) of Form S-4.

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We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Franklin Wyman at 202-551-3660 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Dickerson at 202-551-8013 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Michael Blankenship, Esq. Elizabeth Razzano, Esq.