

November 13, 2020

Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attention: Deanna Virginio

Suzanne Hayes Nudrat Salik Sasha Parikh

Re: BioAtla, Inc.

**Draft Registration Statement on Form S-1** 

Submitted on October 6, 2020

CIK No. 0001826892

#### Ladies and Gentlemen,

On behalf of our client, BioAtla, Inc. (the "Company"), we are responding to the comments from the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") relating to the Company's Draft Registration Statement on Form S-1 (the "Registration Statement") contained in the Staff's letter dated November 3, 2020 (the "Comment Letter"). In response to the comments set forth in the Comment Letter, the Company has revised the Registration Statement and is filing a Registration Statement on Form S-1 (the "Amended Registration Statement") together with this response letter. The Amended Registration Statement also contains certain additional updates and revisions.

Set forth below are the Company's responses to the Staff's comments in the Comment Letter. The responses and information below are based on information provided to us by the Company. For convenience, the Staff's comments are repeated below in bold, followed by the Company's response to the comments as well as a summary of the responsive actions taken. We have included page numbers to refer to the location in the Amended Registration Statement submitted herewith where the revised language addressing a particular comment appears. Capitalized terms used but not defined herein are used herein as defined in the Amended Registration Statement.



<u>Draft Registration Statement on Form S-1</u> <u>Overview, page 1</u>

1. We note statements throughout the prospectus that imply efficacy, such as "[y]our approach affords the necessary targeting and potency required for cancer cell destruction," the "tumor-selective activity markedly improves both safety and efficacy of antibodies against a wide range of targets by widening the therapeutic window, or the possibility for a more effective therapy," that your "CAB technology is validated," that "TmPS, . . . appears to correlate with achievement of clinical response," that you "have developed CAB antibodies with specificity for tumors, while avoiding binding to the same antigen target expressed on many normal tissues," and that you have "invented, developed and refined this technology so that you can effectively and selectively activate proteins and antibodies in the tumor microenvironment." Please revise your disclosure throughout your prospectus to revise these and similar statements to eliminate conclusions or predictions that your product candidates are effective as determinations of efficacy are solely within the authority of the FDA. You may provide a summary of the data that you used to draw these conclusions, and such discussion is more appropriate in the Business section where full and proper context can be provided.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 1-5, 114-118, 124-125 and 127-128 of the Amended Registration Statement.

2. Additionally, we note your disclosure that you have observed "an improved therapeutic window relative to non-CAB products." Please refrain from making such comparisons unless you have conducted head to head trials.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 1, 2, 4, 114, 119 and 125 of the Amended Registration Statement.

3. We note your disclosure that you have initiated potentially registration-enabling Phase 2 trials for your two latest stage ADC product candidates BA3011 (targeting AXL) and BA3021 (targeting ROR2) in multiple cancer indications. Please provide balancing disclosure that the FDA has not opined on whether the Phase 2 clinical trials will in fact be sufficient to support regulatory approval, as you state on page 17, and that there can be no assurance that that the FDA will agree that such data will be sufficient to support approval. Please also provide similar disclosure in your summary risk factor section.



Response: The Company respectfully advises the Staff that it has revised disclosure on pages 1, 3, 6, 17, 20, 114, 117, 128, 141 and 148 of the Amended Registration Statement.

4. We note your disclosure on page 25 that you have developed a quantitative biomarker assay called the Tumor membrane Percent Score, which measures expression levels of AXL and ROR2 on the tumor membrane and cytoplasm. Please provide a brief explanation of the TmPS with respect to AXL and ROR2 and your use of such predictive biomarkers in connection with your Phase 2 trials.

Response: The Company respectfully advises the Staff that the TmPs measures the level of target (such as AXL or ROR2) expression on the tumor membrane which, consistent with industry standards, the Company uses to identify those patients who the Company believes will be the most likely to respond to the Company's product candidates. The Company believes that the higher the level of target expression on the tumor membrane, the more likely it is that the Company's product candidates may have the potential to produce a response. In the Company's BA3011 Phase 1 clinical trials in sarcoma patients, the Company's data suggested that a TmPs of 70% or above correlated with tumor volume reduction of 30% or more. The Company intends to confirm these findings in a Phase 2 study which will enroll up to approximately 90 sarcoma patients with AXL-expressing TmPS greater than 70. An interim analysis will be performed after these patients have had the potential to be followed for at least 12 weeks. The Company, in consultation with the FDA, will then confirm that a TmPS of 70% or above is the appropriate AXL expression cut-off for the second and potentially registration-enabling part of the clinical trial.

Similar to BA3011, the Company's BA3021 Phase 1 clinical trial results in NSCLC and melanoma patient suggested that a TmPS of 50% or above correlated with tumor volume reduction of 30% or more. The Company intends to confirm these findings in a Phase 2 clinical trial which will enroll up to approximately 40 NSCLC and melanoma patients with a ROR2-expressing TmPS greater than 50%. An interim analysis will be performed after these patients have had the potential to be followed for at least 12 weeks. The Company, in consultation with FDA, will then confirm that a TmPS of 50% or above is the appropriate ROR2 expression cut-off for the second and potentially registration-enabling part of the clinical trial.

The Company further respectfully advises the Staff that it has revised disclosure on pages 3, 116, 143 and 149 of the Amended Registration Statement.



### Our Pipeline, page 3

5. We note that you have included in your pipeline table your bispecific antibody programs, which appear to be pre-clinical. Given their materiality, please expand your disclosure on pages 142-143 to provide a more fulsome discussion of these programs. Alternatively, remove any programs that are not currently material from your pipeline table. Additionally, we note your disclosure that you have advanced two CAB bispecific antibody product candidates into investigational new drug, or IND, enabling studies in the second half of 2020. However, based on your pipeline table it appears that all four programs are in IND enabling studies. Please revise the arrows to appropriately reflect whether the programs are in discovery or the IND enabling studies phase.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 3, 116, 128, 153, and 154 of the Amended Registration Statement.

6. We note your completed clinical trials relate to some, but not all of the stated indications. Please explain your basis for depicting the development status with respect to indications that have not been subject to clinical trials. For example, you include Ovarian Cancer in the indication column, however, it does not appear that you have initiated Phase 2 trials for BA3011 or BA3021 for the treatment of Ovarian Cancer.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 3, 116, and 128 of the Amended Registration Statement.

# Our Strengths, page 5

7. We note your statement that your CAB technology is "validated by robust clinical Phase I data from our two leading clinical programs." Additionally, your disclosures beginning on page 111 indicate a correlation between a proprietary biomarker and antitumor activity and antitumor responses resulting from treatment. Generally, the purpose of Phase I trials are to measure and collect data related to safety and dosing. To the extent the trials you have conducted to date were designed to measure and collect data about efficacy, please expand the description of the trials appearing in your business section to quantify the number of participants, describe the trials endpoints, and summarize all the results from the trials, including the p values. Alternatively, if the Phase I trials were not designed to measure and collect information about efficacy relative to trial endpoints, the statements about efficacy appear anecdotal and not appropriate to include in your filing.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 134-137 and 144-145 of the Amended Registration Statement.



### Risks associated with our business, page 6

8. We note your disclosure on page 25 that if the AXL and ROR2 TmPS scores prove to be a useful method for patient selection, you expect to incorporate the specific diagnostic test into your registrational studies and partner with the appropriate diagnostic provider to codevelop a companion diagnostic. Please add a bullet point explaining that if use of any of your product candidates, such as BA3011 and BA3021, depends on a companion diagnostic test then the FDA generally will require approval or clearance of that companion diagnostic, at the same time that the FDA approves your product candidates, as you state on page 25.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 7 and 25 of the Amended Registration Statement.

<u>Implications of being an emerging growth company . . ., page 8</u>

9. Please 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.

Response: The Company is supplementally providing the Staff, under separate cover, with copies of written communications, as defined in Rule 405 under the Securities Act, that have been presented to date by the Company, or individuals authorized to act on the Company's behalf, to potential investors in reliance on Section 5(d) of the Securities Act. To the extent that the Company, or anyone authorized to act on the Company's behalf, presents any such written communications to potential investors in reliance on Section 5(d) of the Securities Act after the date hereof, the Company will supplementally provide the Staff with copies of any such written communications.

#### Risk Factors

Risks related to our common stock and this offering

We are an "emerging growth company" and..., page 70

10. We note that you elected to take advantage of the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. Please expand your risk factor to also state that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates.



Response: The Company respectfully advises the Staff that it has revised disclosure on page 71 of the Amended Registration Statement.

Market, industry and other data, page 77

11. We note your statement that industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information and that no independent source has verified such assumptions. These statements appear to imply a disclaimer of responsibility for this information in the registration statement. Please either delete this statement or specifically state that you are liable for the information related to the market and industry data.

Response: The Company respectfully advises the Staff that it has revised disclosure on page 78 of the Amended Registration Statement.

## LLC Conversion, page 81

12. We note that on July 10, 2020, the Company completed a corporate reorganization. Please revise this section to clearly identify the Company's current organizational structure. Include a diagram showing the Company and its subsidiaries and indicate the respective capital structure (e.g. outstanding preferred stock and debt). We also note that on page  $F \neg 9$ , the Company has certain entities that it considers to be variable interest entities. Please also include such entities.

The Company respectfully advises the Staff that following the July 2020 corporate reorganization and LLC Conversion, the Company is a single legal entity with no consolidated variable interest entities or subsidiaries. Prior to the July 2020 corporate reorganization, the Company had two consolidated subsidiaries, Himalaya Therapeutics SEZC, and its wholly-owned subsidiary, Himalaya Therapeutics HK Limited, which were distributed to shareholders in connection with the July 2020 corporate reorganization.

The Company currently has license agreements with BioAtla Holdings, LLC, Inversagen, LLC, Himalaya Therapeutics SEZC and F1 Oncology, Inc. that represent variable interests in entities that meet the definition of a variable interest entity ("VIE"), but these agreements do not provide the Company with the power to direct the activities that are most significant to the economic success of these entities, so the Company is not the primary beneficiary and does not currently consolidate any VIEs. BioAtla Holdings, LLC, Inversagen, LLC and Himalaya Therapeutics SEZC



are disclosed as related parties due to the fact that Dr. Jay Short, the Company's chairman and chief executive officer, and Carolyn Anderson Short, the Company's Executive Vice President and Chief of Intellectual Property and Strategy, serve as a manager or director of each. BioAtla Holdings, LLC, Inversagen, LLC and Himalaya Therapeutics SEZC are currently inactive and have only nominal assets and liabilities. The Company does not currently have any recorded assets and liabilities as a result of its variable interests in these VIEs (including F1 Oncology) arising from the license agreements.

The Company's capital structure as of September 30, 2020 consists of Series D convertible preferred stock, common stock and warrants to purchase common stock. The outstanding Series D convertible preferred stock was issued to new investors in the Series D preferred stock financing and issued to Himalaya Parent LLC in connection with the conversion of the Company's convertible debt that was outstanding prior to the July 2020 corporate reorganization. All of the Company's common shares are held by Himalaya Parent LLC. The outstanding warrants to purchase common stock are held by certain entities affiliated with Beijing Sinobioway Group Co., Ltd, an entity with which the Company previously had a collaboration. Himalaya Parent does not control BioAtla, Inc. as it does not hold the majority of the voting shares of BioAtla, Inc.

The Company respectfully further advises the Staff that it has not included a diagram to reflect the Company's current organizational structure given the simplicity of the single entity structure. The Company has updated its disclosure on page 82 of the Amended Registration Statement to clarify its relationships with each of the VIEs disclosed in its financial statements.

## Capitalization, page 82

13. We noted that you have issued warrants in connection with certain advisory services the fair value of which will vest upon the completion of your public offering. Please tell us why this compensation is not reflected as a pro-forma adjustment to your accumulated deficit in the capitalization table.

Response: The Company respectfully advises the Staff that the fair value of the warrants as of September 30, 2020 is nominal based on the weighted-average exercise price of \$7.50 per share and the \$0.40 per share fair value of the underlying common stock. In addition, we have early adopted ASU No. 2018-07 on October 1, 2020 and the measurement date of these warrants became fixed in accordance with the guidance. As such, the Company did not include a pro forma adjustment for the warrants and does not to expect to record any charges in the future.

Unaudited Pro Forma Condensed Consolidated Financial Information, page 89



14. Following the Division, it appears that you have succeeded to the remaining business of BioAtla, LLC that was not transferred to BA Holdings or Inversagen, LLC and that you had no prior operations before succession. In this regard, please tell us why audited financial statements and related disclosures of BioAtla, LLC as your predecessor through the acquisition date are not required under Article 8 of Regulation S-X through the date of acquisition along with pro forma financial information giving effect to the "Division" under Article 11 of Regulation S-X.

Response: The Company respectfully advises the Staff that the predecessor's assets and liabilities were transferred to the Company at their historical carrying values. The transfer of the predecessor business to the Company represented a transfer of assets, meeting the definition of a business, between entities under common control, which was accounted for as a "change in reporting entity" under ASC 250, *Accounting Changes and Error Corrections*. Accordingly, the historical financial statements of the transferred business are presented as the historical financial statements of the Company, even for periods prior to the Company's formation. In other words, the predecessor financial statements are shown as the historical financial statements of the Company prior to the Division. This accounting is disclosed in Note 1 to the Company's Consolidated Financial Statements under "Organization" and "LLC Division." As such, furnishing the financial statements required under Article 8 of Regulation S-X would not provide any additional information regarding the predecessor's historical balance sheets, results of operations, or cash flows.

There would be no pro forma adjustments to the historical financial statements of the predecessor to reflect the business transferred to the Company in the Division, as the assets and liabilities that remained in BioAtla Holdings, LLC or that ultimately were transferred by the Company to Inversagen, LLC under the Exclusive License Agreement had no carrying value, historical results of operations, or cash flows.

<u>Management's Discussion and Analysis</u> <u>Research and Development Expense, page 100</u>

15. Please disclose for each period presented the amount of research and development expense incurred for each of your lead product candidates. To the extent that you do not track expenses by product candidate, please disclose that fact and explain why you do not maintain and evaluate research and development costs by project.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 101 and 103 of the Amended Registration Statement.

CAB leverages the low pH found in the tumor microenvironment, page 118



16. Please expand your disclosure on page 118 to explain how to interpret the color key located to the right of the tumor heat map graphic. Please also explain how to interpret the bullet point list of percentages to the right of the graphic.

Response: The Company respectfully advises the Staff that it has revised disclosure on page 122 of the Amended Registration Statement.

# BA3011 Phase 1 clinical trial, page 129

17. We note your disclosure that based upon the overall safety and response rates, the recommended Phase 2 dose is 1.8 mg/kg delivered every two weeks. Please provide a description of how the Phase 1 trial was conducted, including the total number of patients enrolled, number of patients dosed in each cohort, the doses administered within the range, and the number of patients with each type of solid tumor (e.g. sarcoma, pancreatic, NSCLC). Please provide similar disclosure on page 135 with respect to the BA3021 Phase 1 trial.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 134-137 and 144-145 of the Amended Registration Statement.

### Safety, page 134

18. Please revise to define on-target toxicity has been identified to date in patients that received BA 3011 during the Phase 1 trial. Please provide similar disclosure on page 139 with respect to the BA3021 Phase 1 trial.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 135, 140 and 148 of the Amended Registration Statement.

19. We note that you include cross-trial comparisons regarding toxicities observed for other non-CAB ADCs. Please disclose why you believe this comparison is 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 (e.g. number of patients, dosage, types cancers associated with the patients enrolled, etc.).

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 140-141 of the Amended Registration Statement.



20. We note that you disclose the treatment related SAE's observed at the anticipated Phase 2 dose level. Please describe all SAE's observed in the Phase 1 trial for BA3011 and provide similar disclosure on page 139 with respect to the BA3021 Phase 1 trial.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 140-144 and 148 of the Amended Registration Statement.

Clinical development plans, page 135

21. Please expand your discussion of the graphical illustration on page 135 to more clearly explain the Company's clinical development plan for BA3011. Please provide similar disclosure for the graphical illustration on page 140 with respect to the Company's clinical development plan for BA3021.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 141-142 and 148-150 of the Amended Registration Statement.

Global Co-Development and Collaboration Agreement with BeiGene, Ltd., page 146

22. Please revise your summary of the Global Co-Development and Collaboration Agreement with BeiGene, Ltd. to disclose the term of the agreement and the royalty term as well as a summary of the termination provisions under the agreement.

Response: The Company respectfully advises the Staff that it has revised disclosure on page 156 of the Amended Registration Statement.

23. We note that the Company has also entered into license agreements with Himalaya Therapeutics SEZC, Inversagen, LLC, and F1 Oncology Inc. Please include a summary of the material terms associated with each of these agreements.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 157-158 of the Amended Registration Statement.

Intellectual Property, page 147

24. We note your disclosure that as of September 1, 2020, you have 474 patents and patent applications with 254 issued, 7 allowed applications and 213 pending applications. Please expand your disclosure to include the specific technologies to which such patents relate, the type of patent protection, the patent expiration dates and the applicable jurisdictions.



Response: The Company respectfully advises the Staff that it has revised disclosure on pages 160-162 of the Amended Registration Statement.

25. We note your disclosure on page F-9 that the Company's VIE, HTKY, holds intellectual property related to certain CAB Antibodies and is seeking a funding partner to further develop this intellectual property. Please revise to clarify whether any patents or other intellectual property are held by entities other than the Company.

Response: The Company respectfully advises the Staff that it has revised disclosure on pages 160-162 of the Amended Registration Statement.

Principal Stockholders, page 195

26. Please revise to identify the natural persons with voting and/or dispositive control of the shares held by Pfizer Ventures (US) LLP, Soleus Private Equity Fund I, L.P., HBM Healthcare Investments (Cayman) Ltd. in footnotes 2, 3, and 4 to the principal stockholder table.

Response: The Company respectfully advises the Staff that it has revised disclosure on page 210 of the Amended Registration Statement.

Notes to Consolidated Financial Statements
1. Organization and Summary of Significant Accounting Policies
Organization, page F-7

27. Please expand your discussion of BioAtla, LLC's (the Predecessor) business prior to the "Division" and whether there are any continuing operations.

Response: The Company respectfully advises the Staff that it has revised disclosure on page F-8 of the Amended Registration Statement and refers the Staff to its response to comment 14 above noting that the historical financial statements of the transferred business are presented as the historical financial statements of the Company, even for periods prior to the Company's formation.



#### Variable Interest Entities, page F-8

28. Please clearly identify all of the entities you consider to be a Variable Interest Entity and provide the disclosures required by ASC 810-10-50, as applicable. For example, you have identified Inversagen and F1 Oncology to be a variable interest entity.

Response: The Company respectfully advises the Staff that as of and for the year ended December 31, 2019, it had variable interests in three variable interest entities ("VIEs"): i) F1 Oncology, Inc. ii) Inversagen, LLC (a related party) and iii) Himalaya Therapeutics SEZC (a majority owned subsidiary). Neither Inversagen nor Himalaya Therapeutics SEZC had any material assets, liabilities or operations as of and for the year ended December 31, 2019 and, as such, have relatively limited disclosures. The Company believes it met the disclosure objectives of ASC 810-10-50 to provide 1) information about the significant judgments and assumptions made in determining whether it must consolidate the VIEs and the nature of the Company's involvement in the VIE's, 2) the nature of restrictions on a consolidated VIE's assets and on the settlement of its liabilities reported by a reporting entity in its statement of financial position, including the carrying amounts of such assets and liabilities, 3) the nature of, and changes in, the risks associated with a reporting entity's involvement with the VIE and 4) how a reporting entity's involvement with the VIE affects the reporting entity's financial position, financial performance and cash flows. Items 2, 3 and 4 above are not applicable. With respect to Item 1 above, the Company has described the nature of its involvement with Inversagen, LLC (Note 1 – "Organization"), Himalaya Therapeutics SEZC (Note 1 – "Variable Interest Entities") and F1 Oncology, Inc. (Note 11 – "F1 Oncology, Inc.") and provided information with respect to its conclusions regarding not being the primary beneficiary of each entity. In addition, the Company considered the disclosure requirements of ASC 810-10-50-4 (a)-(e) since the Company is not the primary beneficiary of any of the VIE's in which it holds a variable interest, and no incremental disclosures were required. In its Amended Registration Statement, the Company has aggregated its VIE disclosures in Note 9 – "Other related party transactions" an

#### **Exhibits**

29. Please file the promissory note evidencing the Company's PPP loan as an exhibit to the registration statement, pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please explain to us why such disclosure is not appropriate.

Response: The Company respectfully advises the Staff that it has filed the Company's PPP loan as exhibit to the Amended Registration Statement.

\* \* \*



Please contact the undersigned at (202) 261-3440 if you have any questions regarding the foregoing

Sincerely,

/s/ David E. Schulman

David E. Schulman

cc: Jay M. Short, PhD, BioAtla, Inc. David S. Rosenthal, Dechert LLP