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**VIA EDGAR**

April 25, 2022

U.S. Securities and Exchange Commission  
Division of Corporate Finance  
Office of Trade & Services  
100 F Street, N.E. Washington, D.C. 20549  
Attention: Taylor Beech and Katherine Bagley

**Re: bioAffinity Technologies, Inc.  
Draft Registration Statement on Form S-1  
Submitted February 14, 2022  
CIK No. 0001712762**

Dear Ms. Beech and Ms. Bagley:

This response letter (this “**Response**”) is submitted on behalf of bioAffinity Technologies, Inc., (the “**Company**”) in response to the comments that the Company received from the staff of the Division of Corporation Finance (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**SEC**”) in a letter addressed to Ms. Maria Zannes, dated March 15, 2022 (the “**Comment Letter**”), with respect to the Company’s draft registration statement on Form S-1, submitted to the SEC on February 14, 2022 (the “**Registration Statement**”). The Company is concurrently submitting a live, non-confidential filing of its Registration Statement (the “**Live Filing**”), which reflects the changes discussed as part of the Company’s responses to the Staff’s comments in this letter and other updates.

For reference purposes, the Company’s responses are included below each of the Staff’s bolded numbered comments, the text of which have been reproduced from the Comment Letter. All capitalized terms used but not defined in this Response have the meanings ascribed to them in the Live Filing.

The responses below are based on information provided to Dykema Gossett PLLC by the Company.

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**Draft Registration Statement on Form S-1 Submitted February 14, 2022**

**Cover Page**

- We note your disclosure that your officers and directors will control 70% of the voting power of your common stock. Please disclose this on your prospectus cover and in your prospectus summary.**

**RESPONSE:** The Company has revised the Registration Statement to address this comment (see prospectus cover and p. 10).

**Prospectus Summary**

**Overview, page 1**

- We note your disclosure that you intend to “seek approval by the FDA for the nationwide launch of the CyPath Lung product as a lung cancer diagnostic.” Please revise this section and your Business section to prominently clarify whether you are seeking FDA approval of your product as a medical device and specify which FDA approval path you will pursue. Clearly state what stage of the FDA approval process you are at currently and your expected timeframe for approval. Provide comparable disclosure for your statement that you “will launch CyPath Lung as a CE-marked *in vitro* diagnostic test in the European Union.”**

**RESPONSE:** The Company has revised the Registration Statement to address this comment (see p. 8 and p. 56).

- Explain the difference between “a limited market launch of CyPath Lung as an LDT under the Clinical Laboratory Improvement Amendments program administered by the Centers for Medicare and Medicaid Services and guidelines issued by the College of American Pathologists” and the “the nationwide launch of the CyPath Lung product as a lung cancer diagnostic” upon FDA approval that you will seek in Phase 3 of your commercialization strategy, including how the FDA approval will impact your business.**

**RESPONSE:** The Company has revised the Registration Statement to address this comment (see p. 8 and p. 56).

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4. We note the following statements throughout this section and your Business section:

- “CyPath Lung is a well-balanced, accurate test, with both high specificity and sensitivity;”
- “CyPath Lung is accurate;”
- “We developed an automated platform that utilized machine learning to produce high-throughput, user-friendly and accurate analysis of flow cytometric sample data;” and
- “The Company has developed a proprietary platform technology for in vitro diagnostics, the first of which is a highly accurate, noninvasive test for early detection of lung cancer.

As you indicate you are in the process of seeking “FDA approval” for CyPath Lung, and efficacy determinations are solely within the FDA’s authority and they continue to be evaluated throughout all phases of clinical trials, please remove these and any similar references in your prospectus. You may present objective data resulting from your pre-clinical trials or studies without including conclusions related to efficacy.

RESPONSE: The Company has revised the Registration Statement to address this comment. Conclusory statements concerning the efficacy of CyPath Lung have been eliminated throughout the Live Filing and objective data has been included.

5. We note that you refer to CyPath Lung as a “product” and you refer to your other technologies in development as “product candidates.” Given CyPath Lung has not been approved by the FDA, please tell us why it is appropriate to refer to it as a “product” in this context.

RESPONSE: The Company has revised the Registration Statement to address this comment. CyPath<sup>®</sup> Lung is now referred to throughout the Live Filing as a “test” rather than as a “product.”

6. Please ensure that where you present data from your clinical trials, here and throughout your filing, you include a balanced description of each clinical trial, including the number of participants in the trial, length of the trial and number of follow ups, and specify the test data used.

RESPONSE: The Company has revised the Registration Statement to address this comment.

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7. We note your statement that “CyPath Lung has the potential to dramatically increase overall diagnostic accuracy of lung cancer.” Please specify what you mean by “dramatically” increase diagnostic accuracy.

RESPONSE: The Company has revised the Registration Statement to address this comment. The word “dramatically” has been removed and additional supporting information about the potential economic and diagnostic impact of CyPath<sup>®</sup> Lung has been added in a new Appendix I beginning on p. 116.

8. Your prospectus summary should provide a balanced discussion of your business. Therefore, please amend your prospectus summary to include disclosure, as you do on page 46, discussing that, since your inception in 2014, you have generated no revenue from product sales and have funded your operations principally through private sales of your equity or debt securities. Please also discuss your working capital deficit.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 2).

**Business Strategies, page 8**

9. Please revise the discussion here and in your Business section to explain in greater detail your plans for obtaining coverage and reimbursement for CyPath Lung as a lung cancer diagnostic in the U.S., and the EU. Please also specify the timeframe in which you intend to complete each phase of your commercialization plan.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 8 and p. 63).

**The Offering, page 10**

10. We note your disclosure regarding the voting rights of your Series A Preferred Stock and that so long as 30% of the Series A Preferred Stock shares remain outstanding, the holders of your Series A Preferred Stock, will be entitled to elect one director of the Company. Please clarify whether the Series A Preferred Stock will convert into common stock in connection with the IPO and whether the director designation right will continue after your IPO. Please make similar clarifications in your Description of Capital Stock on page 87 when describing your Series A Preferred Stock and on page 76 where you state that Mr. Rubin serves as the director elected by the holders of your Series A Preferred Stock. Finally, to the extent the director designation right will continue after your IPO, describe the same on your prospectus cover page.

RESPONSE: The Company has revised the Registration Statement to address this comment (see the prospectus cover, p. 10 and p. 87).

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**Underwriters' Compensation, page 10**

11. We note your disclosure that “the underwriters will receive an underwriting discount equal to nine percent (9.0%) (subject to reduction) of the offering price of the shares in the Offering.” Please briefly describe the circumstances under which the discount is “subject to reduction.” Please also briefly describe the “certain liabilities” for which you will reimburse the underwriters.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 10).

**Use of Proceeds, page 42**

12. We note your disclosure that you intend to use the proceeds from this offering for working capital and for general corporate purposes, which may include product development. To the extent you plan to use a material portion of the proceeds to fund the development of CyPath Lung, please specify how far in the clinical development for each phase you plan to reach with the proceeds from this offering.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 44).

**Management's Discussion and Analysis of Financial Condition and Results of Operations, page 47**

13. To the extent material, please revise this section to quantify and describe the impact of the COVID-19 pandemic on your business. Please make conforming updates to your risk factor on page 32.

RESPONSE: The Company has revised the MD&A in the Registration Statement to address this comment (see p. 50) and has made conforming updates to the applicable risk factor (see p. 32).

**Company Overview**

**Product Development, page 47**

14. Most of the disclosures in this section are a description of your product which are also contained in the Prospectus Summary and Business sections. Please consider revising MD&A to eliminate this product description and focus the disclosures on your results of operations.

RESPONSE: The Company has revised the MD&A in the Registration Statement to address this comment.

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**Business, page 54**

15. Please revise this section to include a discussion of the effect of existing or probable governmental regulations on your business, including any government approvals you need, such as the Clinical Laboratory Improvement Amendments program administered by the Centers for Medicare and Medicaid Services, guidelines issued by the College of American Pathologists, FDA approval, and CE-marking approval. Your disclosure should include applicable regulations in your targeted markets. Refer to Item 101(h)(4)(viii) and (ix) of Regulation S-K.

RESPONSE: The Company has revised the Registration Statement to address this comment by adding an extensive section on government regulation (see p. 74).

16. We note your disclosure that you have entered into agreements with Smiths Medical to provide Smiths Medical's acapella device with CyPath Lung, with GO2 Partners for kitting, warehousing and distributing patient collection kits, and that you have licensed your intellectual property associated with CyPath Lung to Precision Pathology Services to offer the test for sale. Please describe the material terms of these agreements in this section and file the agreements as exhibits to your registration statement. Alternatively, tell us why you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

RESPONSE: The Company has revised the Registration Statement to address this comment. The reference to an agreement between the Company and Smiths Medical has been eliminated since the relationship that exists between the Company and Smiths Medical is an informal, non-binding relationship. The material terms of the agreement between the Company and GO2 Partners have been described (see p. 61) and the Company's agreement with GO2 Partners will be filed as an exhibit by amendment.

**The Competition for CyPath Lung, page 62**

17. We note your disclosure that your 2022 competitive analysis showed CyPath Lung to be the most accurate test on the market. Please disclose whether you conducted head-to-head trials of CyPath Lung and each of its competitors, and if not, tell us why this statement is appropriate.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 64).



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18. As a related matter, please provide support for your statements about your competitors clinical trials.

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 64).

**bioAffinity Technologies' Diagnostic Product Pipeline, page 65**

19. Please revise your pipeline chart to include a column for each phase of the FDA approval process. In addition, clarify what you mean by "clinical validation." Make conforming edits where you state that Precision Pathology Services has "fully validated" CyPath Lung.

RESPONSE: The Company has revised the Registration Statement to address this comment, including removal of the pipeline chart.

**Our Employees, page 72**

20. Disclose the number of total employees and number of full-time employees. Refer to Item 101(h)(4)(xii) of Regulation S-K.

RESPONSE: The Company has revised the Registration Statement to address this comment by stating that all eleven of its employees are full-time employees (see p. 82).

**Limitations on Director and Officer Liability and Indemnification, page 80**

21. Please amend your risk factor disclosure to include a risk factor describing the limitations on director and officer liability and indemnification discussed here, and related risks to investors. Please also amend your risk factor disclosure to provide a risk factor discussing the anti-takeover effects discussed on page 89.

RESPONSE: The Company has revised the Registration Statement to address this comment by adding two risk factors on pages 40-41 regarding the limitations-of-liability and indemnification provisions in our amended and restated charter and bylaws and the anti-takeover impact of Section 203 of the Delaware General Corporate Law to which the Company will be subject following the Offering.



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**Executive Compensation**

**Grants of Plan-Based Awards, page 83**

22. Please revise this table to include the columns and disclosure required by Item 402(d) of Regulation S-K.

RESPONSE: The Company has revised the Registration Statement to address this comment. The revised table is included on page 94 of the Registration Statement.

**Outstanding Equity Awards as of December 31, 2021, page 83**

23. Please revise this table to include the stock awards described elsewhere in your filing. Refer to Item 404(p) of Regulation S-K.

RESPONSE: We believe this comment was intended to direct the Company to revise the table in accordance with Item 402(p) (rather than Item 404(p)) of Regulation S-K. The Company has revised the Registration Statement to address this comment accordingly (see p. 94).

**Director Compensation, page 84**

24. We note your disclosure that you issued 50,000 options to each of Robert Anderson, Steven Girgenti, Peter Knight, Mohsin Meghji, Gary Rubin, and Maria Zannes as part of their director compensation. Please provide the table required by Item 402(r), including the disclosure required by Item 402(r)(2)(iv) with respect to these option grants.

RESPONSE: The Company has revised the Registration Statement to address this comment by adding the requested table and disclosure to page 95 of the Registration Statement.

**Principal Stockholders, page 84**

25. Please revise the beneficial ownership table to reflect the impact of this offering. Refer to Item 201(b)(2) of Regulation S-K. Please also revise footnote 10 to the table to identify the natural persons who hold voting or dispositive control over the shares beneficially owned by The Harvey Sandler Revocable Trust.

RESPONSE: The Company has revised the Registration Statement to address this comment. The revised table and footnote are on pages 95-96 of the Registration Statement.



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**Certain Relationships and Related Party Transactions, page 86**

26. **Please revise the notes to your financial statements to disclose the nature and significant terms of these related party transactions or explain why you do not believe this is required. Refer to the guidance in ASC 850-10-50-1.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see Note 14 on p. F-22).

27. **Please include the disclosure required by Item 404(b) of Regulation S-K.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 97).

28. **In an appropriate place in your filing, please provide an estimate of the number of shares into which each note discussed in this section will automatically convert upon completion of this offering.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. 97).

**Consolidated Balance Sheet, page F-17**

29. **Please revise to disclose in the notes to the financial statements the breakout and other relevant information for prepaid expenses and other current assets, and other assets. Make corresponding revisions to the notes to the interim financial statements, if material.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see Note 2 on p. F-9).

**Notes to Consolidated Financial Statements**

**Note 2. Summary of Significant Accounting Policies**  
**Fair Value of Financial Instruments, page F-24**

30. **You disclose on page F-27 that you account for the convertible notes payable at fair value. Please revise to include all required disclosures under ASC 820-10-50. Make corresponding changes to the notes to the interim financial statements.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see Note 7 on p. F-14).

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**Note 8. Convertible Preferred Stock and Stockholders' Deficit**  
**Common Stock, page F-29**

31. **Please revise to disclose the pertinent rights and privileges of common stock. Refer to ASC 505-10-50-3.**

RESPONSE: The Company has revised the Registration Statement to address this comment (see p. F-18.)

**Note 9. Stock-Based Compensation, page F-29**

32. **Please revise to disclose the requisite service period and the maximum contractual term of the options granted under your equity incentive plan. Refer to ASC 718-10-50-2(a).**

RESPONSE: The Company has revised the Registration Statement to address this comment (see Note 11 on p. F-18).

**General**

33. **Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications. Please contact the staff member associated with the review of this filing to discuss how to submit the materials, if any, to us for our review.**

RESPONSE: The Company will supplementally provide the Staff with copies of all written communications, as defined in Rule 405 under the Securities Act, that the Company, or anyone authorized to do so on its behalf, present to potential investors in reliance on Section 5(d) of the Securities Act.



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Thank you for your review and consideration of the matters set forth in this Response and in the Live Filing. If you have any questions, please contact the undersigned at (210) 554-5414 or [wliebmann@dykema.com](mailto:wliebmann@dykema.com).

Sincerely,

**Dykema Gossett PLLC**

/s/ Wilhelm E. Liebmann

Wilhelm E. Liebmann, Esq.

cc: Maria Zannes  
Chief Executive Officer  
bioAffinity Technologies, Inc.