



DIVISION OF
CORPORATION FINANCE

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

March 15, 2022

Maria Zannes
Chief Executive Officer
bioAffinity Technologies, Inc.
22211 W Interstate 10
Suite 1206
San Antonio, Texas 78257

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

Dear Ms. Zannes:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

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

Cover Page

1. 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.

Prospectus Summary

Overview, page 1

2. 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."

3. 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.
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.

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.
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.

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.
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.

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.

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.

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.

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.

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.

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.

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.
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.

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

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.

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.

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.

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.

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.

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.

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.

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

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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.

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.

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.

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.

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).

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.

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You may contact Stephen Kim at 202-551-3291 or Theresa Brilliant at 202-551-3307 if you have questions regarding comments on the financial statements and related matters. Please contact Taylor Beech at 202-551-4515 or Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Trade & Services

cc: Wilhelm E. Liebmann, Esq.