



DIVISION OF
CORPORATION FINANCE

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

January 14, 2025

Patrick NJ Schnegelsberg
Chief Executive Officer
Picard Medical, Inc.
4 Palo Alto Square, Suite 200
Palo Alto, CA 94025

**Re: Picard Medical, Inc.
Amendment No. 2 to Draft Registration Statement on Form S-1
Submitted December 26, 2024
CIK No. 0002030617**

Dear Patrick NJ Schnegelsberg:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our December 10, 2024 letter.

Amendment No. 2 to Draft Registration Statement on Form S-1

Prospectus Summary

Our Business, page 1

1. We note your revised disclosure in response to comment 2. Please further revise your disclosure to clarify, at first instance, the difference between a Bridge to Transplantation ("BTT") and Bridge to Candidacy ("BTC") product.
2. We note your revised disclosure in response to comment 5, including that "[t]o our knowledge, there is limited clinical data available to support [the dual LVAD's] safety and efficacy because it has never been part of an FDA-approved clinical trial." Given that statements regarding safety and efficacy are within the purview of the FDA or a

similar regulatory body, please remove this disclosure from your filing. As a related matter, please provide support for your disclosures about the costs of dual LVADs, including your disclosures about reimbursement. Also, tell us whether implantation of a single LVAD is a procedure that competes with your current or future products and if so, revise your disclosure accordingly, including the related costs and reimbursement.

History of SynCardia and SynCardia TAH Development, page 2

3. We note your revised disclosure in response to comment 7, including that since June 2022, you have been "building up resources to address existing deficiencies and to update all documentation to align with MDR requirements and [you] are planning to reapply for an MDR CE mark during 2Q25." Please further revise your disclosure to specify how you intend to address the deficiencies that led to the suspension of your CE mark in December 2021. Please also clarify whether, since 2021, the Company has notified their EU customers of the disclosed issues and suspension.

Clinical Efficacy, page 7

4. We note your revised disclosure that "[o]ne-year survival rates among patients who received the SynCardia TAH in RWD settings range from between 75% and 86.6%, depending on the experience of the center performing the procedures and on patient profiles." Please revise your disclosure to describe how the experience of the centers and patient profiles impacted survival rates, providing specifics about the experience levels of the relevant centers and profiles of the relevant patients. As a related matter, we note your disclosure that you "have over 30 active certified centers and approximately twenty-one active centers that have completed at least one implant during the 24 months preceding the date of this prospectus." Please revise your disclosure to discuss the criteria for certification of these centers and the difference between "active certified centers" and "active centers."

New Product Development, page 8

5. We note your revised disclosure that "Unicorn" prototype iterations have been "shown to work utilizing [y]our standard bench test techniques," and "[f]uture iterations of this design may be small and light enough to be implanted." Please revise your disclosure to clarify next steps in achieving regulatory approval of Unicorn, your intended timeline, and that regulatory approval of this and the other new products discussed in this section is not guaranteed. In addition, please clarify what is meant by "shown to work" in this context.
6. Your revised disclosure indicates that Emperor has "been shown to achieve pulsatile flow with rates of cardiac output that match [y]our on-market SynCardia TAH." Given your disclosure that you expect to perform first-in-animal trials of this system in the first half of 2025, please clarify the trial, study, or test of the Emperor that has "shown" cardiac output matching your on-market product, and clarify what is meant by "match" in this context.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 64

7. Please refer to our prior comment 11. As previously requested, for each period presented, explain the underlying reasons for the increase/decrease in revenues related to sales in the U.S. market.
8. Please refer to our prior comments 12 and 13. As previously requested, for all periods presented, revise to discuss cost of revenues as a percentage of sales and quantify the significant components that led to the change, including the amount of inventory charges in each period.
9. Please refer to our prior comment 14 and address the following comments:
 - Tell us where you provide expanded disclosure that provides more detail for your research and development expenses for each period presented, including but not limited to by product candidate as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such.
 - Explain what you mean by your new disclosure that "While research and development supply expense are isolated by product, personnel are not."

Industry Overview, page 83

10. We note your revised disclosure in response to comment 22, including that your total addressable market for total artificial hearts in the United States exceeds 15,000 patients, or approximately \$2.6 billion, and that your serviceable addressable market is approximately \$200 million for the BTT label and \$500 million for the BTC and long-term indications, based on approximately 2,800 patients. Please revise to provide the underlying data supporting your total addressable market and serviceable addressable market calculations, including the data from your market research, physician interviews, and disclosed sources supporting your patient estimates, and how you arrived at market valuations using these patient estimates. In your discussion, please clarify how you estimated the market for the BTC and long-term indications, given that you have yet to receive regulatory approval to commercialize your product for these indications.

Enforcement of Civil Liabilities, page 101

11. We note your revised disclosure in response to comment 26, including that you conduct certain operations through subsidiaries located outside of the United States and one of your directors resides outside the United States, and that it could be difficult or impossible for investors to effect service of process on you or this individual. Please further revise your disclosure to identify and discuss the difficulties presented by the relevant rules and regulations in the specific countries in which your subsidiaries operate and the country of residence of your director.

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Audited Financial Statements

Note 7. Commitments and Contingencies

(c) China Corporation, page F-19

12. Please refer to our prior comment 29 and address the following comments:
- Please clarify what you mean by SynCardia Beijing's "present form" and explain the nature of their current operations.
 - With reference to the guidance in both Rule 11-01(d) and ASC 805-10-55-3A-55-9, please provide a more detailed analysis to support your belief that SynCardia Beijing is not a business.

Note 9. Temporary Equity and Stockholder's Deficit

(a) Redeemable Convertible Preferred Stock, page F-20

13. Please refer to our prior comment 30. Revise your disclosure to more fully explain the transactions regarding the December 2022 share issuance, similar to your response.

Exhibits

14. Please refile Exhibit 10.41 in the proper text-searchable format. Refer to Item 601(b)(10)(iv) of Regulation S-K and Item 301 of Regulation S-T.

Please contact Julie Sherman at 202-551-3640 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services

cc: Michael J. Blankenship