

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

March 14, 2025

Peter Ludlum Interim Chief Executive Officer Pulmatrix, Inc. 945 Concord Street, Suite 1217 Framingham, MA 01701

Re: Pulmatrix, Inc.
Registration Statement on Form S-4
Filed February 14, 2025
File No. 333-284993

#### Dear Peter Ludlum:

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

# Cover Page

- 1. Please disclose prominently on the prospectus cover page that Cullgen is a Delaware company with significant operations conducted in China through the company's Shanghai subsidiary.
- 2. Provide prominent disclosure about the legal and operational risks associated with being based in or having the majority of the combined company's operations in China. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of the securities you are registering for sale or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to data security or anti-monopoly concerns, have or may impact the company's ability to conduct its

- business, accept foreign investments, or list on a U.S. or other foreign exchange. Please disclose whether Ernst & Young Hua Ming LLP is subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act and related regulations will affect your company. Your Q&A and/or prospectus summary should address, but not necessarily be limited to, the risks highlighted on the prospectus cover page.
- 3. Provide a description of how cash will be transferred through the combined company's organization and disclose your intentions to distribute earnings. State whether any transfers, dividends, or distributions have been made to date between Cullgen and its subsidiary, or to investors, and quantify the amounts where applicable. Provide cross-references to the condensed consolidating schedule and the consolidated financial statements.

# Questions and Answers about the Merger, page 1

- 4. Please revise the Q&A to explain whether Pulmatrix's board would be authorized to implement a reverse stock split and/or an increase to authorized common shares if Proposals 2 and 3 were to pass but Proposal 1 were not to receive stockholder approval.
- 5. We note the disclosure on pages 107 and 319 indicating that Cullgen currently is a subsidiary of GNI Japan. Please add a Q&A to discuss the past, current and future relationship between Cullgen and GNI. For instance, tell us and disclose, as applicable, whether GNI founded Cullgen. Discuss whether GNI and Cullgen's current parent/subsidiary relationship is planned to change as a result of the reverse merger transaction. In light of GNI's significant equity interest in Cullgen and the overlap in their management teams, please discuss whether GNI will control Cullgen's operations. Discuss any material contracts between the parties that will survive the merger, including any arrangements involving funding, tax allocation, technology transfer or provision of services, as applicable.
- 6. Please add a Q&A that discusses Pulmatrix's current plans to sell its historical assets and operations. Discuss risks to Pulmatrix shareholders stemming from uncertainties surrounding these potential sales, including without limitation the potential impact on whether a special dividend is paid and the amount of any such dividend.

# Q: What will Pulmatrix securityholders receive in the Merger?, page 2

7. We note your disclosure here and elsewhere indicating that the Pulmatrix board of directors may declare a pre-closing Special Cash Dividend. Please explain whether Pulmatrix shareholders will know prior to commencement of voting whether the Pulmatrix board is committed to issuing a dividend within the parameters negotiated by the Merger parties.

# <u>Prospectus Summary</u> <u>The Companies, page 12</u>

8. We note your statement claiming that Cullgen's product candidates have distinct advantages including "improved efficacy" over other therapeutic modalities. Given that Cullgen is early in its development efforts, please revise this statement, and any

- others like it, to avoid the implication that Cullgen's product candidates are or will be deemed effective, as such conclusions are within the sole authority of FDA and comparable foreign regulators.
- 9. Please provide a diagram of Cullgen's corporate structure, identifying the person or entity that owns the equity in each depicted entity.
- 10. Disclose each permission or approval that Cullgen and its subsidiaries are required to obtain from Chinese authorities to operate their business and to offer the securities being registered to foreign investors. State whether Cullgen is covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency and state affirmatively whether they have received all requisite permissions or approvals and whether any permissions or approvals have been denied. Please also describe the consequences to investors if they: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future.
- 11. Provide a clear description of how cash will be transferred through the organization. Disclose your intentions to distribute earnings. Quantify any cash flows and transfers of other assets by type that have occurred between Cullgen and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary has made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors.
- 12. Disclose that trading in your securities may be prohibited under the Holding Foreign Companies Accountable Act if the PCAOB determines that it cannot inspect or investigate completely your auditor, and that as a result an exchange may determine to delist your securities. Disclose here whether your auditor is subject to the determinations announced by the PCAOB on December 16, 2021.

#### The Merger

## Background of the Merger, page 101

- 13. Please revise here to disclose the final valuation attributed to Cullgen in the merger agreement.
- 14. Please revise to provide a more fulsome discussion related to the changes in the valuation of Pulmatrix. For example, we note that disclosure here indicates that Pulmatrix was initially valued at \$10 million by the parties on October 25, 2024, but disclosure on page 121 indicates that the final merger agreement values Pulmatrix at \$8 million. Please disclose the parties' reasoning for such changes.
- 15. Please revise to clarify whether Party C made an offer in the August 2024 to October

- 2024 timeframe and when negotiations with Party C terminated.
- 16. We note that Pulmatrix's board considered liquidation scenarios at multiple points during 2024. Please revise to disclose each of the relevant liquidation values assessed. Similarly revise the disclosure on page 106 to identify the liquidation value that Pulmatrix's board considered when rendering its decision at the November 11, 2024 meeting.

#### Pulmatrix's Reasons for the Merger, page 106

17. Please revise the disclosure on page 107 to identify the large pharmaceutical partner and the applicable research and development efforts.

# Cullgen's Business, page 211

18. With reference to the unaudited pro forma financials, please revise to disclose how the combined company plans to allocate funding across the five clinical and preclinical programs identified in the pipeline table on page 215.

# Cullgen's Strengths, page 212

19. We note your statements claiming CG001419 is being developed as a "potential first-in-class" treatment for both pain management and certain cancers. Please revise these statements as they appear to be speculative given the current development status of these product candidates and the noted length and uncertainty of the drug approval processes.

# Cullgen's Strategy, page 213

20. Please revise your disclosures on page 213 to explain the terms "clinically validated" and "clinically relevant."

## Clinical and Preclinical Pipeline, page 215

- 21. Please revise your pipeline table to include a column for Phase 3 to clearly represent all development stages that must be completed prior to submission of your product candidates for regulatory approval.
- 22. We note the inclusion of two "undisclosed" preclinical programs in your pipeline table. Please tell us what aspects of the programs are undisclosed. Please note that we may have additional comment regarding inclusion of these candidates in your pipeline table.

## Phase 1/2 clinical trial, page 220

23. Please revise to identify the treatment emergent adverse event that led to drug discontinuation.

#### Phase 1 clinical trial, page 230

24. Please revise to briefly discuss the material aspects of Cullgen's planned Phase 1 trial of CG009301 in patients with refractory hematologic malignancies including the expected number of patients you will enroll, the location of the trial and planned clinical endpoints.

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### Patents, page 235

25. We note your disclosure regarding the patent and patent applications that Cullgen or its affiliates own. Please revise to identify these affiliates to clarify if you are referring to Cullgen Shanghai, GNI Japan or other entities.

<u>Unaudited Pro Forma Condensed Combined Financial Information</u>
<u>Notes to Unaudited Pro Forma Condensed Combined Financial Statements</u>

3. Adjustments to the Unaudited Pro Forma Condensed Combined Statement of Operations for the Nine Months Ended September 30, 2024 and for the Year Ended December 31, 2023, page 299

26. Please explain why the estimated transaction costs of \$7.9 million, as reflected in Adjustment B, which are not yet reflected in the historical financial statements as of September 30, 2024, and are expected to be incurred by Cullgen in connection with the merger, are not included as an adjustment in the December 31, 2023, Unaudited Pro Forma Condensed Combined Statement of Operations.

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 Christine Torney at 202-551-3652 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Tyler Howes at 202-551-3370 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Alok Choksi, Esq.