



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

DIVISION OF
CORPORATION FINANCE

April 10, 2025

John C.M. Farquhar
Chief Executive Officer
Heartflow, Inc.
331 E. Evelyn Avenue
Mountain View, CA 94041

Re: Heartflow, Inc.

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

Submitted March 27, 2025

CIK No. 0001464521

Dear John C.M. Farquhar:

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 March 5, 2025 letter.

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

Prospectus Summary

Overview, page 1

1. We note your disclosure in response to comment 3, including that your Heartflow FFRct Analysis "calculates blood flow and pinpoints clinically significant CAD, which is CAD with a fractional flow reserve value of .80 or below." Please revise your disclosure to define and explain at first instance the significance of "fractional flow reserve" with respect to coronary artery disease.
2. We note your response to comment 7, including that "all of the approximately 0.4 million patients with acute chest pain with NSTE...will be eligible for [y]our

Heartflow Plaque Analysis." Please revise to briefly explain why you believe that all of these patients will be eligible for your Heartflow Plaque Analysis.

The Offering, page 13

3. We note your disclosure that \$98.4 million of convertible promissory notes will automatically convert with the initial public offering. We also note that \$23 million of outstanding indebtedness under the 2024 Credit Agreement was converted into 2025 Convertible Notes. Please revise your disclosure to include these additional 2025 Convertible Notes.

Risk factors

If we are unable to design, implement and maintain effective internal control over financial reporting.... page 62

4. We note that you previously included a risk factor detailing identified material weaknesses in your internal control over financial reporting, the material adjustments to your fiscal year 2023 financial statements as a result of these material weaknesses, along with adjustments made to your fiscal years 2019 through 2022 financial statements, and the remediation steps that have been implemented to address the material weaknesses. Please expand your risk factor to discuss the previously identified material weaknesses, the remediation steps implemented for the identified material weaknesses, and the status of your testing of your remediation efforts.

We face risks associated with a concentrated customer base, page 62

5. We note your revised disclosure in response to comment 13, including that for the year ended December 31, 2024, your top two largest customers collectively represented approximately 8% of your revenue, and that as you expand the adoption of the Heartflow Platform to new accounts, your customer concentration risk may increase. Please clarify why the addition of new accounts may increase your customer concentration, including whether you expect current customers to open new accounts, and if so, the impact of the same on your growth strategies. Please also explain how you determine an account is "new," given your disclosure that decision-making for accounts is concentrated in a relatively small number of customers.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of operations, page 86

6. Please expand your discussion and analysis of revenue to quantify the impact of the change in utilization and pricing, including the impact of rebates and the change in mix of customer accounts. Also, provide an explanation for the changes in mix of customer accounts. Refer to Item 303(b)(2) of Regulation S-K for guidance.
7. Please expand your discussion and analysis of gross margin to quantify the impact of the increase in revenue versus the automation of manual components of the production teams' process. Refer to Item 303(b)(2) of Regulation S-K and Section 501.12 of the Financial Reporting Codification (i.e., Release 33-8350, Section III.B) for guidance.

Liquidity and capital resources

Sources of liquidity, page 88

8. We note that you no longer believe that there is substantial doubt about your ability to continue as a going concern as of December 31, 2024 due to the 2025 Convertible Notes offering during the first quarter of fiscal year 2025. We further note that as of December 31, 2024, your working capital has decreased, the degree to which total liabilities exceeds total assets has increased, total stockholders' deficit has increased, and you continue to recognize loss from operations and net loss that you expect will continue into the future. As such, please expand your disclosures to provide investors with a balanced outlook about the material factors that have impacted and will continue to impact your liquidity from a short-term and long-term perspective. Also provide a discussion about why the 2025 Convertible Notes issuances provide you with sufficient liquidity to meet all of your obligations within the next 12 months, including the amount of the net proceeds received from the issuances along with how the net proceeds were utilized. Refer to Item 303(b)(1) of Regulation S-K and Section 501.13 of the Financial Reporting Codification (i.e., Release 33-8350, Section IV) for guidance.

Business

Our Clinical Results and Economic Evidence, page 119

9. We note your response to comment 23, including the revised disclosures on pages 119 through 126. Please revise to disclose whether statistical significance was demonstrated, including supporting p-values, as appropriate, for all of the studies cited, specifically the PRECISE and PLATFORM studies. Please also expand upon the "usual care" pathways noted in the PRECISE trial, and explain how your PRECISE trial demonstrated that "NITs are inaccurate a majority of the time, and often result in either missed CAD diagnoses or unnecessary invasive procedures," as disclosed on page 125.

Certain Relationships and Related-Party Transactions, page 162

10. We note your response to comment 26, including your disclosure on page 166 that "[c]ertain of [y]our obligations under the BCLS Letter Agreement will remain in effect after the completion of this offering, including [y]our obligation to obtain the consent of Bain Capital prior to making certain public disclosures about Bain Capital or certain of its affiliates, certain indemnification obligations and certain pro rata lock-up release rights of Bain Capital." Please revise to further discuss these indemnification obligations and pro-rata lock-up release rights.

18. Subsequent Events, page F-39

11. Please expand your disclosure for the 2025 Convertible Notes to disclose the net proceeds and effective interest rate.

April 10, 2025

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Please contact Tracey Houser at 202-551-3736 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Juan Grana at 202-551-6034 or Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services

cc: Ryan Coombs, Esq.