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

DIVISION OF
CORPORATION FINANCE

March 5, 2025

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

Re: Heartflow, Inc.
Draft Registration Statement on Form S-1
Submitted February 6, 2025
CIK No. 0001464521

Dear John C.M. Farquhar:

We have reviewed your 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.

Draft Registration Statement on Form S-1 submitted February 6, 2025

Cover Page

1. We note your disclosure on page 62 that, after this offering, certain of your executive officers, directors, owners of more than 5% of your capital stock, and their affiliates will have the ability to influence you through their ownership position, including the potential ability to determine all matters requiring stockholder approval. Please revise your cover page to include disclosure describing the control of these shareholders and affiliates.

Prospectus Summary, page 1

2. Here and throughout your registration statement where you provide disclosure regarding the industry in which you operate, your competitors, and market statistics,

please provide support for your disclosures, including, as applicable, the basis for management's opinions or beliefs. For example only, we note the following statements:

- "We estimate that there were approximately 9.5 million non-invasive tests (“NITs”) in the United States in 2023 for patients experiencing stable or acute chest pain, which we refer to as symptomatic CAD patients;"
- Stress-based NITs are "inaccurate, a majority of the time, and often result in either missed CAD diagnoses or unnecessary invasive procedures;" "approximately 20-50% of patients who undergo stress-based NITs go home with false negative or undetected CAD;" and "up to 55% of patients receive false positives;"
- "We estimate that as of December 31, 2023, there were approximately 2,700 hospitals and outpatient facilities in the United States that perform CCTA, and this target account base has grown at a 10% CAGR from 2018 to 2023;" and
- "With the elevation of CCTA to a Class 1, Level A guideline recommendation by the AHA and ACC guidelines in 2021, CCTA test volumes have grown at a 22% CAGR from 2018 to 2023 while SPECT volumes have grown at a 2% CAGR over the same time period."

Please make conforming changes throughout your filing, including to your description of your business, competition, and the industry in which you operate.

Overview, page 1

3. We note your disclosure on page 2 that "Heartflow FFRCT Analysis calculates blood flow and pinpoints functionally significant CAD at every point in the major coronary arteries, guiding decisions on whether a patient requires invasive revascularization." Please define "functionally significant."

4. We note your disclosure on page 3 that "[t]he CCTA + Heartflow FFRCT Analysis pathway is supported by the American Heart Association (“AHA”) and American College of Cardiology (“ACC”) guidelines, with CCTA identified as a Class 1, Level A test and Heartflow FFRCT Analysis identified as a Class 2a, Level B test," "Heartflow FFRCT Analysis is reimbursed under a dedicated Category 1 Current Procedural Terminology (“CPT”) code," and "A Category 1 CPT code was also recently established for Heartflow Plaque Analysis, which will take effect in January 2026, and it is covered by all seven Medicare administrative contractor (“MACs”)." Please revise your disclosure here or provide a cross reference to more detailed disclosure in the filing to further explain the various classes, levels and reimbursement categories pursuant to current clinical guidelines and reimbursement policies, including those of the AHA and ACC. We also note your disclosure on page 103 that "CCTA now has guideline support from the European Society of Cardiology Clinical Practice guidelines on Chronic Coronary Syndromes (1B), is included in the National Institute for Health and Care Excellence (“NICE”) guidelines in the United Kingdom, and in the Japanese Circulation Society (“JCS”) 2022 Guidelines in Japan." Please revise to discuss the significance of receiving guideline support from each of these institutions.

5. We note your disclosure on page 22 that the Heartflow Platform relies on a CCTA first being performed, and that companies performing CCTA could determine to develop, partner with, or acquire and offer a product that competes with the Heartflow Platform, or manufacture CT scanners that are no longer compatible with the Heartflow Platform. Please revise your summary to discuss the Heartflow Platform's reliance on third-party CCTAs and compatible CT scanners, including any risks or limitations related to this reliance.

6. Please revise to disclose your accumulated deficit for the fiscal years ended December 31, 2024 and 2023.

Our symptomatic CAD market opportunity, page 5

7. We note that you discuss estimates for your market opportunity in the United States throughout your filing. Please address the following issues related to your market opportunity estimates:

   - You disclose on page 2 that you estimate your current market opportunity in the United States is approximately $5 billion, and that you believe "Heartflow FFRCT Analysis is applicable to approximately 33% of NIT patients annually and the majority of patients experiencing acute chest pain, which represents 3.1 million patients and an estimated market opportunity of approximately $3.3 billion in the United States." Please provide support for your statements regarding the number of patients "experiencing acute chest pain," including sources for this information and clarify how you arrived at a market opportunity of $3.3 billion based on this estimate. Include a discussion of the material assumptions underlying your estimates, including price per product, reimbursement rates, etc.
   - As a related matter, we note your disclosure on page 5 that "Heartflow FFRCT Analysis is reimbursed for use on any CCTA showing 40% to 90% stenosis, which [you] estimate to be approximately 33% of all CCTAs annually," and that you "believe that CCTA + Heartflow FFRCT Analysis therefore is applicable to 33% of the NIT market and a majority of patients experiencing acute chest pain, which represents 3.1 million patients and an estimated market opportunity of approximately $3.3 billion in the United States." Please provide the data, sources, and assumptions underlying your estimates of stenosis, patients, and market opportunity and explain how you calculated an estimated market opportunity in the US of approximately $3.3 billion based on these estimates. Please also clarify whether your estimated market opportunity is based on patients with a CCTA showing 40% to 90% stenosis, or "a majority of patients experiencing acute chest pain."
   - You disclose that "[w]e believe our Heartflow Plaque Analysis is applicable to approximately 60% of NIT patients annually and the majority of patients experiencing acute chest pain, which represents 5.5 million patients and an estimated market opportunity of an incremental approximately $1.7 billion in the United States." Please provide the data and assumptions supporting your estimates related to the proportion of NIT patients and number of patients disclosed. In addition, please discuss how your "limited market education efforts" for

Heartflow Plaque Analysis impact your market opportunity estimates for this product.

8. We note your disclosure that your current focus is on the United States but that you "also have a commercial presence and regulatory approval in certain international markets, including the United Kingdom, European Union and Japan, which [you] estimate represents an additional 4.2 million potential CCTA patients." Please provide relevant sources, data, and assumptions supporting your estimate of the potential CCTA patients in these international markets.

The Offering, page 12

9. We note your disclosure that "[i]n connection with the completion of this offering, [you] are obligated to use certain of the net proceeds from this offering to repay $50.0 million (or $55.0 million if the underwriters exercise their option to purchase additional shares of common stock) of the indebtedness outstanding under the amended credit agreement and guaranty (the “2024 Credit Agreement”) with Hayfin Services, LLP (“Hayfin”) and to pay...fees in connection therewith." Please revise to briefly discuss your relationship to Hayfin, including the percentage of your beneficial ownership held by entities affiliated with Hayfin.

10. Please revise your disclosure to describe the lock-up agreements discussed on pages 63 and 179 of your registration statement.

Summary consolidated financial data, page 15

11. Please expand your statement of operations and balance sheet pro forma presentations to include an adjustment for the stock-based compensation expense for the restricted stock unit that will be granted concurrently with the offering as disclosed on page 13, along with disclosures that disclose the material terms of the grant, the total amount of compensation expense to be recognized, the period over which the expense will be recognized, and the assumptions used to estimate the compensation expense. Refer to Article 11-02(a)(8) of Regulation S-X for guidance. Please address this comment for all of your pro forma presentations.

12. Please expand your statement of operations pro forma presentation to include an adjustment for the interest expense and change in fair value of derivative liability, if any, associated with the $50 million repayment for the 2024 Credit Agreement. Please address this comment for all of your pro forma presentations.

Risk Factors
To date we have derived a significant amount of our revenue from a small number of customers, and face risks associated with a more..., page 21

13. We note your disclosure that "although [y]our Heartflow Platform had an installed base of over 1,100 accounts in the United States as of December 31, 2024, the decision-making function for many of these accounts is concentrated in a relatively small number of customers, such that the loss of one customer could result in a disproportionate loss across [y]our accounts." We also note your disclosure on page 82 that "[n]o single customer accounted for 10% or more of [y]our revenue during the year ended December 31, 2023." Please revise, here and on page 82, to reconcile these

two statements, including whether a "disproportionate loss" across accounts would result in a similar loss to your revenue, and note whether any customer accounted for more than 10% of your revenue during the year ended December 31, 2024. Please also revise your disclosures on page 82 to clarify the difference, if any, between your installed base of accounts and customers.

Our Heartflow Platform and the data and models it generates could have bugs, defects or errors, including human quality control errors..., page 25

14. We note your disclosure that "[you] have in the past, and may in the future, experience defects or errors in [y]our Heartflow Platform or the data and models it generates that remain undetected by [y]our analyst-based review process." Please revise to briefly discuss, if material, these prior defects or errors in the Heartflow Platform or the data and models it generates, including any related negative impacts on your business or operations. We also note your disclosure on page 39 that "[yo]ur products have been in the past, and may in the future, be the subject of medical device reports of adverse events with the FDA's Manufacturer and User Facility Device Experience database, including reports of false negative results and incorrect or imprecise results or readings." Please revise to briefly discuss these past medical device reports of adverse events, if material, including any reports of false negative results and incorrect or imprecise results or readings, and the related impact on your business or operations.

Off-label or other unlawful promotion of our products could result in costly investigations and sanctions from the FDA and other..., page 39

15. We note your disclosure here and throughout the filing that the Heartflow Platform has been "cleared by the FDA, and the equivalent regulatory authorities in Israel, Saudi Arabia, United Arab Emirates, licensed in Bahrain, CE Marked in the European Economic Area, the United Kingdom and Australia, received medical device licensing in Canada and been approved for marketing authorization in Japan by the Pharmaceuticals and Medical Devices Agency ("PMDA"), all for specific indications for use." We also note your disclosure on page 125 that "[o]nly the FFRCT Analyses is authorized for clinical use in the European Economic Area, United Kingdom, Australia, Canada, and Japan," and that the "Heartflow Platform is regulated in the United States by the FDA as a Class II medical device." Here and in your prospectus summary, please revise to note, as you do on page 25, the specific FDA authorization received by your Heartflow Platform and each of the products within your Heartflow Platform. Please also revise your disclosure on page 39 to clarify that only the FFRCT, and not your Heartflow Platform, is authorized for clinical use in the EEA, the UK, Australia, Canada, and Japan. Please also briefly discuss, or cross-reference to your disclosures elsewhere, the significance of CE Mark, PMDA, and medical device licensing approval outside of the United States. Finally, we note your disclosure on page 36 that you "currently have ongoing responsibilities under U.S., U.K., European Economic Area, Switzerland, Canada, Australia, Japan, Saudi Arabia, United Arab Emirates, Bahrain and Israel (registered or licensed regions) regulations." Please revise to clarify the nature of the ongoing responsibilities, including whether each of your products is authorized for clinical use in each of these listed jurisdictions.

Market and Industry Data, page 70

16. We note your disclosure that "[t]his prospectus contains estimates, projections, and other information concerning our industry and our business, as well as data regarding market research, estimates, and forecasts prepared by our management or third parties, including but not limited to, Clarivate." Please revise your disclosure throughout to cite to specific sources prepared by third parties, where appropriate. In addition, please tell us whether you commissioned any industry or market data that you reference in the prospectus, including from Clarivate. If so, file consents of the relevant third parties pursuant to Rule 436 of the Securities Act as exhibits to your registration statement.

Use of Proceeds, page 71

17. We note your disclosure that "[you] expect to use the remainder of the net proceeds from this offering, together with [y]our existing cash and cash equivalents, to fund [y]our sales and marketing efforts, fund research and product development activities and for other general corporate purposes, including working capital, operating expenses, and capital expenditures." Please revise to briefly discuss these planned research and product development activities, including the specific product(s) for which you intend to use these proceeds. Refer to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Components of our results of operations, page 82

18. We note your disclosure that key factors that drive your revenue include expanding the adoption of the Heartflow Platform in new accounts and expanding the utilization of your system in existing accounts. To provide context to investors for your statements about your growth potential, please revise to clarify the amount or percentage of your revenue cases attributable to existing compared to new accounts for the relevant financial quarters presented on page 82. As a related matter, please clarify how you determine whether an account is "active."

Results of Operations, page 84

19. We note your disclosure that your increase in revenue was primarily attributable to an increase in volume, partially offset by a modest reduction in average sales price. Please clarify the reason for this reduction, and disclose whether you expect this trend to continue in future financial periods.

Contractual Obligations and Commitments, page 90

20. We note your disclosure that "[you] entered into various exclusive technology licensing agreements that require [you] to make annual royalty payments in fixed amounts as well as certain milestone and revenue-based payments." In an appropriate place in your filing, please disclose the material terms of these licensing agreements and file the agreements as exhibits to your registration statement, or provide your analysis as to why these agreements are not required to be filed. Refer to Item 601(b)(10) of Regulation S-K.

Business
Our Success Factors, page 97

21. We note your disclosure that "[y]our proprietary database of more than 100 million annotated CCTA images, growing daily, has fueled ongoing AI-driven algorithm refinement for over a decade—enhancing [y]our platform's value for patients, physicians, and payors." Please revise to provide additional detail regarding the development of your proprietary database, including your source(s) for the more than 100 million annotated CCTA images.

22. We note your disclosure that utilization rates for Heartflow FFRCT Analysis typically scale rapidly after onboarding, approaching approximately 33% of eligible CCTA tests within an account. Please clarify how you calculate utilization rates, including the period by which you measure these rates, and provide additional detail describing the significance of utilization rates to your business and operations, including how these rates translate into increasing Heartflow revenue cases.

Our Clinical Results and Economic Evidence, page 114

23. We note your disclosure that "[t]he accuracy, clinical utility and economic benefits of [y]our Heartflow Platform have been evaluated in over 100 clinical studies and more than 130,000 patients, including two large randomized controlled trials, with results published in over 600 peer-reviewed clinical publications." We also note your disclosure beginning on page 144 detailing some but not all of the trials, studies, and research you reference throughout your filing. Where you reference certain trials, studies, or research supporting your disclosure, please identify the specific source to which you refer. In addition, please revise to discuss your material clinical studies, trials and any other research cited in further detail. In particular, please disclose the date(s) and location(s) of the studies and trials; the sponsor(s); the number of participants, including how participants were selected; the results of the studies and trials, including how results were measured; key assumptions; any serious adverse events; and whether statistical significance was demonstrated, including supporting p-values, as appropriate. Please also disclose whether any of the parties involved, including the sponsors in the studies and trials, are affiliates or partners of Heartflow. As an example only, we note that you have included references to certain studies which are not discussed in detail in the registration statement, such as the SCOT-HEART randomized controlled trial and the FAME 1 and FAME 2 RCTs.

Intellectual Property, page 122

24. We note your disclosure on page 123 that "[a]ssuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable, [y]our owned and licensed issued U.S. patents expire between 2018 and 2041." Please revise to clarify which of your patents have expired, and disclose which of your patents will expire in the near-term.

Certain Relationships and Related-Party Transactions, page 155

25. Please revise to clarify the relationship between Hayfin Services, LLP and Hayfin HeartFlow UK Limited.

26. Please revise to disclose the related parties, including your directors and officers and holders of more than 5% of your capital stock and affiliates, that are parties to the investor rights agreement, the voting agreement, the right of first refusal and co-sale agreement and the management rights letters. Refer to Item 404 of Regulation S-K. We also note your disclosure on page 159 that "[c]ertain of [y]our obligations under the BCLS Letter Agreement will remain in effect after the completion of this offering, including certain indemnification obligations." Please revise to discuss the obligations that will remain in effect.

27. We note your disclosure on page 160 that "[you] have entered into change in control and severance agreements with [y]our executive officers that, among other things, provide for certain compensatory and change-in-control benefits, as well as severance benefits." Please revise to disclose the material terms of these agreements and file the agreements as exhibits to your registration statement. Refer to Item 601(b)(10) of Regulation S-K. We also note your disclosure that "[you] have entered into indemnification agreements with certain of [y]our current directors and executive officers and intend to enter into new indemnification agreements with each of [y]our current directors and executive officers before the completion of this offering." Please file the form of indemnification agreement as an exhibit to your registration statement.

2. Summary of Significant Accounting Policies
Revenue Recognition, page F-12

28. Please expand your disclosures to address the following:
    - Provide the payment terms disclosures required by ASC 606-10-50-12.b.
    - Address whether you have needed to make any material adjustments to the variable consideration estimates.

7. Commitments and Contingencies, page F-22

29. Please provide the disclosures required by ASC 450-20-50 for legal proceedings and/or litigation. In this regard, we note the disclosures provided on page 137.

General

30. We note that you make various statements throughout the registration statement regarding your leadership in your field and the efficacy of your products including, but not limited to, the following:

    - Page 1: CCTA has become the "preferred" first-line test for patients with suspected CAD.
    - Page 2: Improved workflow through your Heartflow RoadMap Analysis "reduces CCTA interpretation times by approximately 25% and reduces variability between reviewing physicians by approximately 50%," which leads to "more consistent diagnoses and standardized patient care."
    - Page 3: You believe your platform is the "most extensively studied AI-enabled test for CAD," and "[i]ts accuracy, clinical utility and economic benefits have been evaluated in over 100 clinical studies and more than 130,000 patients, including two large randomized controlled trials, with results published in over

600 peer-reviewed clinical publications."

- Page 4: "CCTA has been clinically demonstrated to have the highest diagnostic performance of all traditional non-invasive imaging test for CAC" and "superior diagnostic accuracy."
- Page 7: Your Heartflow FFRCT Analysis has "the highest diagnostic accuracy for a non-invasive CAD test and has demonstrated a high level of concordance to invasive fractional flow reserve ('FFR')."
- Page 7: "The Heartflow Plaque Analysis has been validated against the reference standard of invasive intravascular ultrasound (“IVUS”) and shown to have a 95% agreement with IVUS in quantifying total coronary plaque volume."
- Page 106: You estimate that "there are approximately 200 million patients globally with a high risk of cardiovascular events, of which 71 million live in the United States. In the future, we believe certain sub-segments of this population may be appropriate candidates for our platform."

Please revise your disclosure throughout the registration statement to provide the basis for any statements, including those above, related to leadership in your field and the efficacy of your products. Please also ensure you disclose any relevant metrics or material assumptions upon which these statements are based, and include cross-references to any clinical studies, trials, or research supporting these statements.

31. 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 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.