

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to ____

Commission File Number: 001-42790

Heartflow, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

331 E. Evelyn Avenue
Mountain View, California
(Address of Principal Executive Offices)

26-0506743
(I.R.S. Employer
Identification No.)

94041
(Zip Code)

Registrant's telephone number, including area code: (650) 241-1221

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	HTFL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of October 31, 2025, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 85,158,719.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. We intend such forward-looking statements contained in this Quarterly Report on Form 10-Q to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management, and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "may," "will," "shall," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," "goal," "objective," "seeks," or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions.

Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding our future results of operations and financial positions, plans for our current and future products, anticipated product launches, the impact of macroeconomic conditions, industry and business trends, and our expectations regarding business strategy, plans, market growth, regulatory climate, competitive landscape and our objectives for future operations.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations, estimates, forecasts, and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. Forward-looking statements involve known and unknown risks and uncertainties and are subject to other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, those factors discussed in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q, as such risks and uncertainties may be amended, supplemented or superseded from time to time by our subsequent periodic reports on Form 10-Q and Form 10-K we file with the United States Securities and Exchange Commission. We qualify all of our forward-looking statements by these cautionary statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

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Part I. Financial Information

Item 1. Condensed Consolidated Financial Statements (unaudited)

Heartflow, Inc. Condensed Consolidated Balance Sheets (in thousands, except share and per share amounts) (unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 291,167	\$ 51,367
Accounts receivable, net	27,858	24,639
Restricted cash, current	—	150
Prepaid expenses and other current assets	8,761	6,132
Total current assets	327,786	82,288
Property and equipment, net	7,984	8,920
Operating lease right-of-use assets, net	17,108	18,805
Restricted cash, non-current	4,475	4,325
Other non-current assets	7,045	4,366
Total assets	\$ 364,398	\$ 118,704
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,958	\$ 2,870
Accrued expenses and other current liabilities	30,368	25,319
Operating lease liabilities, current	5,523	5,416
Total current liabilities	37,849	33,605
Term loan	—	136,431
Common stock warrant liability	55,421	20,835
Operating lease liabilities, non-current	16,266	18,537
Other non-current liabilities	294	214
Total liabilities	109,830	209,622
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock issuable in series, \$0.001 par value; none and 122,231,454 shares authorized, issued and outstanding as of September 30, 2025 and December 31, 2024, respectively; aggregate liquidation value of none and \$951,917 as of September 30, 2025 and December 31, 2024, respectively	—	768,566
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 50,000,000 and no shares authorized as of September 30, 2025 and December 31, 2024, respectively; no shares issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value; 250,000,000 and 210,300,000 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 83,473,696 and 6,122,048 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	83	6
Additional paid-in capital	1,318,352	112,241
Accumulated other comprehensive loss	(512)	(772)
Accumulated deficit	(1,063,355)	(970,959)
Total stockholders' equity (deficit)	254,568	(859,484)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 364,398	\$ 118,704

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Heartflow, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts) (unaudited)

	2025	2024	2025	2024
Revenue	\$ 46,276	\$ 32,934	\$ 126,904	\$ 90,831
Cost of revenue	10,861	7,997	30,770	22,632
Gross profit	35,415	24,937	96,134	68,199
Operating expenses:				
Research and development	17,297	11,863	46,253	31,238
Selling, general and administrative	33,217	28,003	96,197	82,125

	Three Months Ended September 30, 2024		Nine Months Ended September 30, 2024	
Total operating expenses	50,514	39,866	142,450	113,363
Loss from operations	(4,929)	(4,929)	(16,164)	(16,164)
Interest income	820	820	3,474	3,474
Interest expense	(3,451)	(5,298)	(15,165)	(17,616)
Change in fair value of common stock warrant liability	(32,117)	(585)	(34,586)	(4,490)
Change in fair value of derivative liability	4,818	—	7,311	(222)
Loss on extinguishment of debt	(6,360)	—	(6,360)	—
Other income (expense), net	(341)	852	(94)	615
Loss before provision for income taxes	(50,825)	(19,140)	(92,307)	(63,403)
Provision for income taxes	(30)	—	(89)	(48)
Net loss	\$ (50,855)	\$ (19,140)	\$ (92,396)	\$ (63,451)
Comprehensive loss:				
Net loss	\$ (50,855)	\$ (19,140)	\$ (92,396)	\$ (63,451)
Other comprehensive loss:				
Foreign currency translation gain (loss)	205	(405)	260	(504)
Total comprehensive loss	\$ (50,650)	\$ (19,545)	\$ (92,136)	\$ (63,955)
Net loss per share, basic and diluted	\$ (1.04)	\$ (3.43)	\$ (4.47)	\$ (12.24)
Weighted-average shares used to compute net loss per share, basic and diluted	49,106,752	5,586,424	20,686,526	5,185,007

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Heartflow, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share and per share amounts)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	122,231,454	\$ 768,566	6,122,048	\$ 6	\$ 112,241	\$ (772)	\$ (970,959)	\$ (859,484)
Issuance of common stock upon exercise of stock options	—	—	130,813	—	578	—	—	578
Stock-based compensation expense	—	—	—	—	2,492	—	—	2,492
Foreign currency translation loss	—	—	—	—	—	(236)	—	(236)
Net loss	—	—	—	—	—	—	(32,345)	(32,345)
Balance at March 31, 2025	122,231,454	768,566	6,252,861	6	115,311	(1,008)	(1,003,304)	(888,995)
Issuance of common stock upon exercise of stock options	—	—	136,583	—	852	—	—	852
Stock-based compensation expense	—	—	—	—	2,253	—	—	2,253
Foreign currency translation gain	—	—	—	—	—	291	—	291
Net loss	—	—	—	—	—	—	(9,196)	(9,196)
Balance at June 30, 2025	122,231,454	768,566	6,389,444	6	118,416	(717)	(1,012,500)	(894,795)
Conversion of redeemable convertible preferred stock to common stock upon IPO	(122,231,454)	(768,566)	51,226,348	51	768,515	—	—	768,566
Issuance of common stock upon IPO, net of underwriting discounts, commissions and offering costs	—	—	19,166,667	19	332,318	—	—	332,337
Conversion of convertible notes to common stock upon IPO, net	—	—	6,470,743	6	94,133	—	—	94,139
Issuance of common stock upon exercise of stock options	—	—	220,494	1	1,010	—	—	1,011
Stock-based compensation expense	—	—	—	—	3,960	—	—	3,960
Foreign currency translation gain	—	—	—	—	—	205	—	205
Net loss	—	—	—	—	—	—	(50,855)	(50,855)
Balance at September 30, 2025	—	\$ —	83,473,696	\$ 83	\$ 1,318,352	\$ (512)	\$ (1,063,355)	\$ 254,568

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	122,231,454	\$ 768,566	4,940,925	\$ 5	\$ 97,465	\$ (501)	\$ (874,533)	\$ (777,564)
Issuance of common stock upon exercise of stock options	—	—	10,561	—	77	—	—	77
Stock-based compensation expense	—	—	—	—	2,723	—	—	2,723
Foreign currency translation gain	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(20,932)	(20,932)
Balance at March 31, 2024	122,231,454	768,566	4,951,486	5	100,265	(500)	(895,465)	(795,695)
Issuance of common stock upon exercise of stock options	—	—	613,614	1	1,616	—	—	1,617
Stock-based compensation expense	—	—	—	—	2,640	—	—	2,640
Foreign currency translation loss	—	—	—	—	—	(100)	—	(100)
Net loss	—	—	—	—	—	—	(23,379)	(23,379)
Balance at June 30, 2024	122,231,454	768,566	5,565,100	6	104,521	(600)	(918,844)	(814,917)
Issuance of common stock upon exercise of stock options	—	—	260,692	—	1,501	—	—	1,501
Stock-based compensation expense	—	—	—	—	2,336	—	—	2,336
Foreign currency translation loss	—	—	—	—	—	(405)	—	(405)
Net loss	—	—	—	—	—	—	(19,140)	(19,140)
Balance at September 30, 2024	122,231,454	\$ 768,566	5,825,792	\$ 6	\$ 108,358	\$ (1,005)	\$ (937,984)	\$ (830,625)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Heartflow, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	2025	2024
Cash flows from operating activities:		
Net loss	\$ (92,396)	\$ (63,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,069	3,767
Stock-based compensation expense	8,705	7,699
Amortization of debt discount and debt issuance costs	5,367	1,473
Amortization of right-of-use asset	2,258	2,033
Change in fair value of common stock warrant liability	34,586	4,490
Change in fair value of derivative liability	(7,311)	222
Loss on extinguishment of debt	6,360	—
Non-cash interest charges	1,071	1,097
Change in allowance for credit losses	(171)	—
Changes in assets and liabilities:		
Accounts receivable, net	(3,048)	(2,539)
Prepaid expenses and other current assets	(2,629)	(1,431)
Other non-current assets	(2,679)	(1,436)
Accounts payable	(919)	(1,600)
Accrued expenses and other current liabilities	5,955	(2,869)
Operating lease liabilities	(2,725)	(2,380)
Other non-current liabilities	80	(38)
Net cash used in operating activities	(43,427)	(54,963)
Cash flows from investing activities		
Purchase of property and equipment	(3,126)	(4,025)
Net cash used in investing activities	(3,126)	(4,025)
Cash flows from financing activities		
Proceeds from IPO, net of offering costs	332,784	—
Proceeds from convertible notes offering, net of issuance costs	72,769	—
Proceeds from exercise of stock options	2,441	3,195
Repayment of principal under term loan	(115,137)	—
Payments of exit, prepayment penalty and lender fees	(6,764)	(1,809)
Net cash provided by financing activities	286,093	1,386
Effect of foreign exchange rates	260	(504)
Net increase (decrease) in cash, cash equivalents and restricted cash	239,800	(58,106)
Balance, beginning of period	55,842	127,234

Balance, end of period	\$	295,642	\$	69,128
Supplemental disclosure of cash flow information:				
Cash paid (refunded) for taxes	\$	89	\$	(72)
Cash paid for interest	\$	8,573	\$	15,067
Supplemental disclosure of non-cash investing and financing activities:				
Purchases of property and equipment included in accounts payable	\$	7	\$	59
Derecognition of derivative liability in connection with debt refinancing	\$	—	\$	1,125
Right-of-use asset obtained in exchange for lease obligation	\$	561	\$	—
Conversion of redeemable convertible preferred stock to common stock upon IPO	\$	768,566	\$	—
Conversion of convertible notes to common stock upon IPO	\$	94,139	\$	—
Conversion of term loan principal to convertible notes	\$	23,000	\$	—
Issuance of convertible notes to certain employees in lieu of cash compensation	\$	1,353	\$	—
Reclassification of term loan debt discount to convertible notes debt discount	\$	239	\$	—
Unpaid IPO offering costs included in accounts payable and accrued expenses and other current liabilities	\$	447	\$	—

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Heartflow, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Business Overview

Description of Business

HeartFlow Holding, Inc. was incorporated in the state of Delaware in July 2007 as Cardiovascular Simulation, Inc. and changed its name to HeartFlow, Inc. in May 2009. On March 1, 2021, HeartFlow, Inc. completed an internal reorganization in which a newly formed parent holding company, HeartFlow Holding, Inc., was established.

On July 17, 2025, HeartFlow Holding, Inc.'s stockholders and Board of Directors approved the consolidation of HeartFlow Holding, Inc. with and into HeartFlow, Inc., with HeartFlow, Inc. continuing as the surviving company. The previous holders of HeartFlow Holding, Inc.'s common stock and preferred securities became holders of HeartFlow, Inc.'s common stock and preferred securities based on a 1-to-1 conversion ratio, and the equity incentive plan, outstanding equity awards, outstanding warrants and certain other equity-related agreements of HeartFlow Holding, Inc. were assumed by HeartFlow, Inc. In connection with this consolidation, HeartFlow, Inc. changed its name to Heartflow, Inc. (the "Company").

The Company is a commercial-stage medical technology company that has pioneered the use of software and artificial intelligence ("AI") to deliver a non-invasive solution for diagnosing and managing coronary artery disease ("CAD"). The Company's novel Heartflow Platform uses AI and advanced computational fluid dynamics to create a personalized 3D model of a patient's heart based off a single coronary computed tomography angiography ("CCTA"). This results in actionable data on blood flow, stenosis, plaque volume and plaque composition. The Company's Heartflow FFR_{CT} Analysis and Plaque Analysis software assists physicians in diagnosing, managing and delivering precision care to patients with CAD. The Company was awarded Conformité Européenne Mark for its Heartflow FFR_{CT} Analysis in July 2011. The Company received clearance from the U.S. Food and Drug Administration ("FDA") in November 2014 for its Heartflow FFR_{CT} Analysis and in October 2022 for its Plaque Analysis.

The Company's headquarters is located in Mountain View, California, and the Company also has offices in Santa Rosa and San Francisco, California, Austin, Texas, and Tokyo, Japan.

The Company had the following wholly-owned subsidiaries as of September 30, 2025:

Entity Name	Country of Incorporation
HeartFlow Japan G.K.	Japan
HeartFlow U.K. Ltd	United Kingdom
HeartFlow Technology U.K. Limited	United Kingdom

Effective July 2024, HeartFlow International Sarl, a wholly-owned subsidiary in Switzerland, was dissolved.

Reverse Stock Split

On July 31, 2025, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to immediately effect a reverse stock split of the shares of the Company's outstanding common stock at a ratio of 1.0-for-2.92 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, options to purchase common stock, share amounts, per share amounts, and related information contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced, and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's redeemable convertible preferred stock, which automatically

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Heartflow, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

converted into shares of common stock upon the closing of the Company's initial public offering ("IPO") of common stock, were proportionally adjusted.

Initial Public Offering

On August 11, 2025, the Company completed its IPO of 19,166,667 shares of its common stock, which included an additional 2,500,000 shares of common stock purchased by the underwriters pursuant to their option to purchase additional shares, at a price to the public of \$19.00 per share. The gross proceeds to the Company from the IPO were approximately \$364.2 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company of \$31.8 million. Immediately prior to the closing of the Company's IPO, all of the outstanding shares of the Company's redeemable convertible preferred stock converted into shares of the Company's common stock. Additionally, upon the closing of the Company's IPO, the aggregate outstanding principal balance under the 2025 Convertible Notes (as defined in Note 2) automatically converted into shares of the Company's common stock.

Liquidity

The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of approximately \$1.1 billion and \$971.0 million as of September 30, 2025 and December 31, 2024, respectively. The Company expects to incur losses for the foreseeable future. Historically, the Company's activities have been financed through sales of shares of redeemable convertible preferred stock, common stock and convertible promissory notes, borrowings under term loans and revenue received from customers.

As of September 30, 2025, the Company had \$291.2 million in cash and cash equivalents.

Based on the Company's current operating plan, the Company believes that the expected cash generated from revenue transactions with customers and its existing cash and cash equivalents will be sufficient to fund the Company's planned operating expenses and capital expenditure requirements for at least the next 12 months from the date these condensed consolidated financial statements were available to be issued.

However, the Company may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue, or operating expenses and may need to raise additional capital to fund operations, further research and development activities, or acquire, invest in, or license other businesses, assets, or technologies. The Company's future capital needs will depend upon many factors, including the market's acceptance of the Company's products, the cost and pace of developing new products, and the costs of supporting sales growth.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company as well as its wholly owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to a fair statement of the Company's consolidated financial position as of September 30, 2025, and the results of its operations for the three and nine months ended September 30, 2025 and 2024 and cash flows for the nine months ended September 30, 2025 and 2024. The condensed consolidated balance sheet at December 31, 2024, was derived from audited annual consolidated financial statements but does not contain all of the footnote disclosures from the annual financial statements. These interim financial results are not

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Heartflow, Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

necessarily indicative of results expected for the full fiscal year or for any subsequent interim period and should be read in conjunction with the annual consolidated financial statements included in the Company's registration statement on Form S-1 (File No. 333-288733), which became effective on August 7, 2025.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management used significant judgment when making estimates in the determination of the fair value of its common stock and stock options, deferred income tax valuation allowance, capitalized internal-use software, depreciation of property and equipment, allowance for credit losses, revenue recognition, valuation of operating lease right-of-use ("ROU") assets and operating lease liabilities, and the fair value of convertible debt, common stock warrant liability and derivative liability. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions as facts and circumstances dictate. Actual results could materially differ from those estimates.

Segment Information

The Company operates and manages its business as one reportable and operating segment, which is the business of non-invasive CAD detection solutions. The Company's Chief Executive Officer, who is the Chief Operating Decision Maker ("CODM"), reviews financial information, including revenue and net loss, presented on a consolidated basis for purposes of making operating decisions, allocating resources and evaluating financial performance.

The Company's measure of segment profit or loss is consolidated net loss, which is used by the CODM to measure actual results versus expectations, set performance metrics, and develop the annual budget to achieve the Company's long-term objectives. Significant segment expenses within consolidated net loss includes cost of revenue, research and development, and selling, general and administrative expenses, which are each separately presented on the Company's condensed consolidated statements of

operations and comprehensive loss. Other expense items that are presented on the condensed consolidated statements of operations include interest income, interest expense, changes in fair value of warrant liability, other income, net, and provision for income taxes.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment and includes a reconciliation to the consolidated net loss shown in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2025 and 2024 (in thousands):

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Heartflow, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	\$ 46,276	\$ 32,934	\$ 126,904	\$ 90,831
Less ⁽¹⁾ :				
Cost of revenue	10,861	7,997	30,770	22,632
Research and development expenses:				
Research and development	10,260	6,986	27,582	19,107
Regulatory and clinical	7,037	4,877	18,671	12,131
Selling, general and administrative expenses:				
Sales	18,869	16,981	54,307	49,943
Marketing	4,650	3,564	13,812	9,416
General and administrative	9,698	7,458	28,078	22,766
Loss from operations	(15,099)	(14,929)	(46,316)	(45,164)
Other income (expense), net ⁽²⁾	(35,726)	(4,211)	(45,991)	(18,239)
Provision for income taxes	(30)	—	(89)	(48)
Segment net loss	<u>\$ (50,855)</u>	<u>\$ (19,140)</u>	<u>\$ (92,396)</u>	<u>\$ (63,451)</u>

- (1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.
(2) Other income (expense), net represents the consolidated amounts for interest income, interest expense, change in fair value of common stock warrant liability, change in fair value of derivative liability, loss on extinguishment of debt and other income (expense), net as shown on the condensed consolidated statements of operations and comprehensive loss.

The Company derives revenue and has long-lived assets primarily in the United States of America. Revenue by geography is further described in Note 3.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments that are readily convertible to known amounts of cash and purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

The following table provides a reconciliation of cash, cash equivalents and restricted cash to the total shown in the condensed consolidated statements of cash flows (in thousands):

	September 30,	
	2025	2024
Cash and cash equivalents	\$ 291,167	\$ 64,661
Restricted cash	4,475	4,467
Total cash, cash equivalents and restricted cash	<u>\$ 295,642</u>	<u>\$ 69,128</u>

As of September 30, 2025 and December 31, 2024, restricted cash represents deposits held as security in connection with the Company's facility lease agreements.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

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The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The accounting guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability.

As of September 30, 2025 and December 31, 2024, the carrying amounts of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities and market interest rates, if applicable. Management believes that the Company's Term Loan (as defined in Note 8) and 2025 Convertible Notes (as defined below in this Note 2) then outstanding bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of these instruments approximated their fair value as of December 31, 2024. Fair value accounting is applied to the common stock warrant liability and derivative liability. No derivative liability was outstanding as of September 30, 2025 or December 31, 2024.

Concentration of Credit Risk and Significant Customers

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents, restricted cash and accounts receivable. The Company maintains bank deposits in federally insured financial institutions, and these deposits may at times exceed federally insured limits. To date, the Company has not experienced any losses on its cash deposits. The Company currently has full control of its cash and cash equivalents balance.

No single customer represented more than 10% of the Company's revenue during the three and nine months ended September 30, 2025 and 2024.

No single customer represented more than 10% of the Company's accounts receivable as of September 30, 2025 and December 31, 2024.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. As of September 30, 2025 and December 31, 2024, deferred offering costs of \$0 and \$413,000, respectively, were capitalized within other non-current assets in the condensed consolidated balance sheets. The deferred offering costs were reclassified as a reduction to equity as a result of the closing of the IPO in August 2025.

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Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time.

An ROU asset and corresponding lease liability are recorded on the condensed consolidated balance sheets based on the present value of lease payments over the lease term. An ROU asset represents the right to control the use of an identified asset over the lease term, and a lease liability represents the obligation to make lease payments arising from the lease. Leases with an initial term of 12 months or less are not recorded in the condensed consolidated balance sheets. The Company uses its incremental borrowing rate to determine the present value of lease payments, as the discount rate implicit in the lease is not readily available. The lease terms used to calculate the ROU asset and related lease liabilities include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company elected to account for contracts that contain lease and non-lease components as a single lease component. For the three and nine months ended September 30, 2025 and 2024, the Company's only leases were for its facilities, which are classified as operating leases with lease expense recognized on a straight-line basis over the lease term. Variable lease costs, which primarily consist of common area maintenance, taxes, and utility charges, are expensed as incurred. The Company does not have any finance leases.

Term Loan

Prior to its repayment in August 2025, the Term Loan (as defined in Note 8) was accounted for at amortized cost. Original debt issuance costs were deferred and presented as a reduction to the carrying value of the Term Loan. Debt discount and debt issuance costs were amortized using the effective interest method and recorded in interest expense within the condensed consolidated statements of operations and comprehensive loss. See Note 8 for information about the repayment of the 2024 Term Loan and termination of the 2024 Credit Agreement.

Upon repayment of the 2024 Term Loan, the remaining unamortized debt discount and debt issuance costs were recognized as a loss on extinguishment of debt within the condensed consolidated statements of operations and comprehensive loss.

2025 Convertible Notes

The Company issued convertible notes in January 2025 and March 2025 (the "2025 Convertible Notes") to various investors and certain employees (the "Requisite Holders"), which were accounted for at amortized cost. Debt issuance costs were deferred and presented as a reduction to the carrying value of the 2025 Convertible Notes prior to its conversion upon the IPO. The Company determined that certain features of the 2025 Convertible Notes contained embedded derivatives that provided the Requisite Holders with multiple settlement alternatives, and the embedded features that qualified as derivatives were accounted for separately. Debt discount and debt issuance costs were amortized using the effective interest method and recorded to interest expense within the condensed consolidated statements of operations and comprehensive loss. The Company recognized the changes in fair value of the derivative liability as changes in fair value of derivative liability within the condensed consolidated statements of operations and comprehensive loss through the IPO date. Upon the closing of the Company's IPO, the aggregate principal balance of the 2025 Convertible Notes of \$98.3 million converted into 6,470,743 shares of common stock, and the derivative liability balance of \$24.6 million and the remaining unamortized debt discount and debt issuance costs of \$28.8 million were reclassified to additional paid-in capital. Refer to Note 9 and Note 13 for additional information.

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Common Stock Warrants

The Company's warrants to purchase common stock that were issued in connection with the Term Loan are classified as a liability. The warrants are recorded at fair value upon issuance and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized as a change in fair value of common stock warrant within the condensed consolidated statements of operations and comprehensive loss. Refer to Note 12 and Note 18 for additional information.

Embedded Derivatives

Prior to its refinancing in June 2024, the Term Loan (as defined in Note 8) contained certain prepayment features, a default put option and default interest adjustment features that were determined to be embedded derivatives requiring bifurcation and separate accounting as a single compound derivative, as discussed in Note 13. The impact of bifurcation of the embedded derivative on the date of issuance was reflected as a debt discount. The fair value of the derivative liability related to the Company's Term Loan, as discussed in Note 8, was estimated using a scenario-based analysis comparing the probability-weighted present value of the Term Loan payoff at maturity with and without the bifurcated features. This method isolates the value of the embedded derivative by measuring the difference in the host contract's value with and without the isolated features. The resulting cash flows are discounted at the Company's borrowing rate, as adjusted for fluctuations in the market interest rate from the inception of the Company's comparative borrowings to the reporting date, to measure the fair value of the embedded derivative. Until its derecognition in June 2024, the derivative liability was remeasured to fair value at each reporting period, and the related change was reflected as change in fair value of derivative liability on the condensed consolidated statements of operations and comprehensive loss.

Prior to their conversion upon the IPO, the 2025 Convertible Notes contained certain settlement features and default put options that were determined to be embedded derivatives requiring bifurcation and separate accounting as a single compound derivative, as discussed in Note 13. The impact of the bifurcation of the embedded derivatives on the date of issuances in January and March 2025 was reflected as a debt discount. The fair value of the derivative liability related to the Company's 2025 Convertible Notes, as discussed in Note 9, were estimated using a scenario-based analysis comparing the probability-weighted present value of the 2025 Convertible Notes with and without the bifurcated features. This method isolates the value of the embedded derivatives by measuring the difference in the host contract's value with and without the isolated features. To measure the fair value of the embedded derivatives, the resulting cash flows were discounted using appropriate discount rates that reflect the overall implied risk of the instruments based on their purchase prices and adjusted for fluctuations in the market and Company interest rates when necessary. Prior to the Company's IPO, the derivative liability was remeasured to fair value at each reporting period and the related change was reflected as a change in fair value of derivative liability on the condensed consolidated statements of operations and comprehensive loss until the conversion of the 2025 Convertible Notes in connection with the IPO in August 2025.

Redeemable Convertible Preferred Stock

Prior to its IPO, the Company recorded redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs, which was classified outside of stockholders' equity (deficit) because the preferred shares were contingently redeemable upon the occurrence of an event that is outside of the Company's control. Upon the closing of the Company's IPO, all shares of convertible preferred stock then outstanding automatically converted into an aggregate of 51,226,348 shares of common stock. Refer to Note 10 for additional information.

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Revenue Recognition

The Company sells its Heartflow Platform to medical providers in the United States and in select international markets. The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

The Company identified a single performance obligation, which is comprised of a highly interdependent bundle of goods or services that are not distinct on their own but are as a group and consists of providing implementation services and the requested analysis, including an image file and related licenses and support. Revenue recognition commences only after completion of installation, implementation and training for new customer accounts. The Company's service consists of providing a visualization of the patient's coronary arteries and enables physicians to create more effective treatment plans. This service is normally billable upon delivery of the analysis to the physician. Payment terms are generally net 30 days.

Substantially all of the Company's revenue is from usage-driven fees and generated on a "pay-per-click" basis each time a physician orders the Company's Heartflow FFR_{CT} Analysis and Plaque Analysis. Revenue is recognized when control of these services is transferred to the customer, at an amount that reflects the consideration the Company expects to be entitled to receive in exchange for those services. The Company recognizes usage-driven fee revenue upon delivery of the requested analysis to the physician, which is when control of these services is transferred to the customer. The Company recognizes revenue on a straight-line basis over the contract term for subscriptions where the customer pays a fixed amount upfront for unlimited analyses. Contracts with customers typically include a fixed amount of consideration and are generally cancellable with 30 days' written notice.

The transaction price consists of fixed consideration and variable consideration related to utilization and volume rebates for reimbursement claims from government and commercial payors which are known and determinable based on the number of analyses delivered within each quarterly period. The transaction price (inclusive of both fixed consideration and variable consideration that is not constrained) is recognized as revenue when control transfers. The Company uses a portfolio approach to estimate variable consideration using the expected value method.

Unbilled Receivables

Unbilled receivables generally represent revenue in which the Company has satisfied its performance obligation prior to invoicing. The Company records unbilled receivables within accounts receivable, net on the condensed consolidated balance sheets, based on the Company's unconditional right to payment at the end of the applicable period.

Contract Costs

Costs associated with product revenue include a flat rate commission per analysis and new customer site commissions as well as implementation and onboarding costs. The Company capitalizes new customer site commissions and certain contract fulfillment costs, which include implementation and onboarding costs that are considered to be incremental to the acquisition of new customer contracts. Capitalized contract fulfillment costs are amortized over an estimated period of benefit of two years and capitalized new site commission costs are amortized over an estimated period of benefit of three years. The estimated period of benefit is determined by evaluating average customer life, the nature of the related

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benefit, and the specific facts and circumstances of the arrangements. The Company evaluates these assumptions at least annually and periodically reviews whether events or changes in circumstances have occurred that could impact the period of benefit.

The Company expenses flat rate commissions when incurred as commensurate with its usage-driven fee revenue recognition and amortizes capitalized new customer site commissions to selling, general and administrative expense in the condensed consolidated statements of operations and comprehensive loss. The Company amortizes capitalized contract fulfillment costs to cost of revenue in the condensed consolidated statements of operations and comprehensive loss. Short-term capitalized contract costs are included in prepaid expenses and other current assets, and the long-term portion is included in other non-current assets in the condensed consolidated balance sheets.

Remaining Performance Obligations

Revenue allocated to remaining performance obligations represents the transaction price allocated to performance obligations that are unsatisfied, or partially unsatisfied. It includes contract liabilities and

amounts that will be invoiced and recognized as revenue in future periods and does not include contracts where the customer is not committed. The customer is considered not committed when they are able to terminate for convenience without payment of a substantive penalty under the contract. Additionally, as a practical expedient, the Company has not disclosed the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

Contract Liabilities

The Company records contract liabilities when billings or payments are received in advance of revenue recognition from subscription services. The contract liabilities balance is reduced as the revenue recognition criteria is met, generally within 12 months. Once services are available to customers, the Company records amounts due in accounts receivable, net and contract liabilities within accrued expenses and other current liabilities on the condensed consolidated balance sheets. To the extent the Company bills customers in advance of the billing period commencement date, the accounts receivable and corresponding contract liabilities amount are netted to zero on the condensed consolidated balance sheets, unless such amounts have been paid as of the balance sheet date.

Cost of Revenue

Cost of revenue includes, but is not limited to, personnel and related expenses, stock-based compensation costs, third-party hosting fees, amortization of capitalized internal-use software, amortization of contract fulfillment costs as well as royalties associated with technology licenses used in connection with the delivery of the Company's Heartflow Platform and allocated overhead, including rent, equipment, depreciation, technology services and utilities, related to the Company's production team. The role of the production team is to support the Company's patient case volume revenue by performing defined quality-related activities on CCTA scans submitted by its customers for analysis. The production team also supports activities in the Company's clinical trials and research and development, which are allocated as research and development expense.

Stock-Based Compensation

The Company accounts for share-based payments at fair value. The grant date fair value of options granted is measured using the Black-Scholes option pricing model. Option awards vest based on the satisfaction of a service requirement, and stock-based compensation expense is recorded on a straight-line basis over the applicable service period, which is generally four years. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions. Forfeitures are recognized in the period in which the forfeiture occurs.

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The Company accounts for stock-based compensation for restricted stock units at their fair value, based on the closing market price of the Company's common stock on the date of grant. These costs are recognized on a straight-line basis over the requisite service period, which is usually the vesting period.

The Company accounts for stock-based compensation for its employee stock purchase plan based on the estimated fair value of the options on the date of grant. The Company estimates the grant date fair value using the Black-Scholes option pricing model for each purchase period. These costs are recognized on a straight-line basis over the offering period.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. As a result of the history of net operating losses, the Company has provided for a full valuation allowance against the deferred tax assets for assets that are not more-likely-than-not to be realized.

The Company applies a comprehensive model for the recognition, measurement, presentation and disclosure in the condensed consolidated financial statements of any uncertain tax positions that have been taken or are expected to be taken on a tax return using a two-step approach. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained upon examination by the relevant taxing authorities, based on the technical merits of the position. For tax positions that are more likely than not to be sustained upon audit, the second step is to measure the tax benefit in the financial statements as the largest benefit that has a greater than 50% likelihood of being sustained upon settlement. Significant judgment is required to evaluate uncertain tax positions. Changes in facts and circumstances could have a material impact on the Company's effective tax rate and results of operations. The Company recognizes interest and penalties, if any, related to unrecognized tax benefits as a component of provision for income taxes in the condensed consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss is comprised of net loss and foreign currency translation gains and losses.

Foreign Currency

The functional currency of the Company's foreign subsidiaries is the local currency except for HeartFlow International Sarl, which was the U.S. Dollar. For all non-functional currency balances, the remeasurement of such balances to the functional currency results in either a foreign exchange transaction gain or loss, which is recorded within other income, net within the condensed consolidated statements of operations and comprehensive loss. The Company recognized foreign exchange transaction loss of \$(342,000) and \$(587,000) during the three months ended September 30, 2025 and 2024, respectively, and \$(95,000) and \$(782,000) during the nine months ended September 30, 2025 and 2024, respectively. The Company recognized \$205,000 and \$(405,000) during the three months ended September 30, 2025 and 2024, respectively, and \$260,000 and \$(504,000) during the nine months ended

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For

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purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, common stock warrants and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and common stock subject to repurchase are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Diluted net loss per share is the same as basic net loss per share because the effects of potentially dilutive items were anti-dilutive given the Company's net loss position during the three and nine months ended September 30, 2025 and 2024.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024. The adoption of ASU 2023-09 is expected to have a disclosure only impact on the Company's consolidated financial statements for the year ended December 31, 2025.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The amendments may be applied either (i) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (ii) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of this pronouncement on the disclosures in its consolidated financial statements.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets that arise from transactions accounted for under Accounting Standards Codification Topic 606: *Revenue from Contracts with Customers*. The practical expedient permits an entity to assume that current conditions as of the balance sheet date do not change for the remaining life of the current accounts receivable and current contract assets. This ASU is effective for fiscal years beginning after December 15, 2025 on a prospective basis, and for interim periods within fiscal years beginning after

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December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this pronouncement on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends certain aspects of the accounting for and disclosure of software costs under ASC 350-40 by removing all references to project development stages and provides new guidance on how to evaluate whether the probable-to-complete recognition threshold has been met to begin capitalizing software

costs. This ASU is effective for fiscal years beginning after December 15, 2027 and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The ASU may be applied on a prospective, retrospective or modified prospective basis. The Company is currently evaluating the impact of the adoption of this pronouncement on its consolidated financial statements.

3. Revenue and Contract Balances

Disaggregation of Revenue

The following table summarizes total revenue from customers by geographic region (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
United States	\$ 42,946	\$ 30,170	\$ 117,230	\$ 82,970
United Kingdom	1,519	1,301	4,533	3,802
Japan	1,462	1,109	4,183	3,100
Rest of Europe	349	354	958	959
Total revenue	<u>\$ 46,276</u>	<u>\$ 32,934</u>	<u>\$ 126,904</u>	<u>\$ 90,831</u>

Revenues by geography are determined based on the region of the Company's contracting entity, which may be different than the region of the customer.

Contract Balances

Unbilled receivables included within accounts receivable on the condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024 was \$224,000 and \$574,000, respectively.

The following table provides the breakdown of capitalized contract costs on the condensed consolidated balance sheets (in thousands):

	Nine Months Ended September 30, 2025	Year Ended December 31, 2024
Balance at beginning of period	\$ 6,154	\$ 2,941
Contract costs capitalized	7,188	6,952
Contract costs amortized	(4,207)	(3,739)
Balance at end of period	<u>\$ 9,135</u>	<u>\$ 6,154</u>

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The following table provides the breakdown of contract liabilities included within accrued expenses and other current liabilities on the condensed consolidated balance sheets (in thousands):

	Nine Months Ended September 30, 2025	Year Ended December 31, 2024
Balance at beginning of period	\$ 182	\$ 498
Contract liabilities added	42	—
Contract liabilities recognized as revenue	(75)	(316)
Balance at end of period	<u>\$ 149</u>	<u>\$ 182</u>

4. Fair Value Measurement

The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2025			Total
	Level 1	Level 2	Level 3	
Assets				
Money market funds included in cash and cash equivalents	\$ 262,997	\$ —	\$ —	\$ 262,997
Total	<u>\$ 262,997</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 262,997</u>
Liabilities				
Common stock warrant liability	\$ —	\$ —	\$ 55,421	\$ 55,421
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 55,421</u>	<u>\$ 55,421</u>

	Level 1	Level 2	Level 3	Total
Assets				
Money market funds included in cash and cash equivalents	\$ 36,882	\$ —	\$ —	\$ 36,882
Total	<u>\$ 36,882</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 36,882</u>
Liabilities				
Common stock warrant liability	\$ —	\$ —	\$ 20,835	\$ 20,835

Total	\$	—	\$	December 31, 2024	\$	20,835	\$	20,835

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The following tables present a reconciliation of the Company's financial liabilities measured at fair value as of September 30, 2025 and December 31, 2024 using significant unobservable inputs (Level 3) and the change in fair value (in thousands):

	Common Stock Warrant Liability
Fair value as of January 1, 2024	\$ 4,440
Change in fair value	16,395
Fair value as of December 31, 2024	20,835
Change in fair value	34,586
Fair value as of September 30, 2025	<u>\$ 55,421</u>

In determining the fair value of the common stock warrant liability, the Company used the Black-Scholes option pricing model to estimate the fair value using unobservable inputs including the expected term, expected volatility, risk-free interest rate and dividend yield (see Note 12).

	Term Loan Derivative Liability
Fair value as of January 1, 2024	\$ 903
Change in fair value	222
Derecognition in connection with debt refinancing	(1,125)
Fair value as of December 31, 2024	<u>\$ —</u>

In determining the fair value of the term loan derivative liability, a two-step valuation approach was employed, which included a probability-weighted scenario valuation method, the Black-Scholes-Merton method, and the option pricing method, using unobservable inputs (see Note 13), which are classified as Level 3 within the fair value hierarchy, and then comparing the instrument's value with and without the derivative features to estimate their combined fair value. The debt instrument is carried at amortized cost, which approximates its fair value.

	2025 Convertible Notes Derivative Liability
Fair value as of January 1, 2025	\$ —
Recognition in connection with convertible notes offering	31,900
Change in fair value	(7,311)
Derecognition upon conversion into common stock upon IPO	(24,589)
Fair value as of September 30, 2025	<u>\$ —</u>

In determining the fair value of the convertible notes derivative liability, a two-step valuation approach was employed, which included a probability-weighted scenario valuation method, the Monte Carlo Simulation method, and the option pricing method, using unobservable inputs (see Note 13), which are classified as Level 3 within the fair value hierarchy, and then comparing the instrument's value with and without the derivative features to estimate their combined fair value. The debt instrument is carried at amortized cost, which approximates its fair value.

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5. Balance Sheet Components

Allowance for Credit Losses

The following table presents a reconciliation of the allowance for credit losses (in thousands):

	Nine Months Ended September 30, 2025	Year Ended December 31, 2024
Balance at beginning of period	\$ 814	\$ 1,058
Additions	—	—
Write-offs	(171)	(244)
Balance at end of period	<u>\$ 643</u>	<u>\$ 814</u>

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following (in thousands):

	September 30, 2025	December 31, 2024
Prepaid expenses	\$ 5,372	\$ 3,017
Contract costs, current	2,453	2,453
Other	936	662
Total prepaid expenses and other current assets	<u>\$ 8,761</u>	<u>\$ 6,132</u>

Property and equipment, net

Property and equipment consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Property and equipment at cost:		
Computer equipment and software	\$ 4,503	\$ 4,489
Furniture, fixtures and equipment	1,578	1,233
Capitalized internal-use software	55,104	52,606
Leasehold improvements	2,145	2,057
Construction in progress	215	27
Total property and equipment	63,545	60,412
Less: Accumulated depreciation and amortization	(55,561)	(51,492)
Property and equipment, net	<u>\$ 7,984</u>	<u>\$ 8,920</u>

The Company capitalized certain internal-use software costs totaling \$971,000 and \$1.3 million, including stock-based compensation of \$6,000 and \$121,000, related to internal-use software development efforts, during the three months ended September 30, 2025 and 2024, respectively, and \$2.5 million and \$2.1 million, including stock-based compensation of \$17,000 and \$198,000, during the nine months ended September 30, 2025 and 2024, respectively. Amortization of capitalized internal-use software totaled \$951,000 and \$761,000 for the three months ended September 30, 2025 and 2024, respectively, and \$3.0 million and \$1.5 million for the nine months ended September 30, 2025 and 2024, respectively.

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Depreciation and amortization expense related to property and equipment, excluding capitalized internal-use software, was \$352,000 and \$413,000 for three months ended September 30, 2025 and 2024, respectively, and \$1.1 million and \$885,000 for the nine months ended September 30, 2025 and 2024, respectively.

Other Non-Current Assets

Other non-current assets are comprised of the following (in thousands):

	September 30, 2025	December 31, 2024
Contract costs, net	\$ 6,681	\$ 3,701
Deferred offering costs	—	413
Other	364	252
Total other non-current assets	<u>\$ 7,045</u>	<u>\$ 4,366</u>

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities are comprised of the following (in thousands):

	2025	2024
Accrued payroll and related expenses	\$ 23,057	\$ 18,206
Customer contract and rebate liabilities	520	1,041
Accrued royalty	1,015	736
Accrued professional fees	2,274	1,672
Accrued clinical trial expenses	962	1,215
Other	2,540	2,449
Total accrued expenses and other current liabilities	<u>\$ 30,368</u>	<u>\$ 25,319</u>

6. Leases

The Company leases office space in Mountain View, California, San Francisco, California (Refer to Note 18), Santa Rosa, California, Austin, Texas, and Tokyo, Japan.

Mountain View, California

In August 2021, the Company entered into a facility lease agreement with MV Campus Owner, LLC (the "Landlord") for approximately 61,000 rentable square feet in Mountain View, California through August 2030. In connection with the lease, the Company established a standby letter of credit for the benefit of the Landlord in the amount of \$4.3 million in August 2021, which is classified as non-current restricted cash on the condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024.

Santa Rosa, California

In October 2024, the Company entered into an agreement to sublease approximately 4,000 rentable square feet of office space in Santa Rosa, California for 29 months commencing on November 1, 2024. In connection with this sublease, the Company paid a security deposit of \$8,000 and recorded an ROU asset and lease liability of \$169,000.

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Austin, Texas

In January 2023, the Company amended its facility lease agreement in Austin, Texas, which provided for approximately 26,000 square feet of space, to extend the original lease term which expired in November 2023 with a five-year renewal option to December 2025 with no renewal option. In September 2025, the Company amended the lease for its Austin, Texas facility to extend the lease term an additional 12 months through December 2026 and recorded an ROU asset and lease liability of \$561,000 in connection with the lease extension. A security deposit of \$150,000 was recorded as non-current restricted cash as of September 30, 2025 and as current restricted cash as of December 31, 2024, on the condensed consolidated balance sheets related to this lease.

Tokyo, Japan

The Company has one non-cancellable operating lease for its facility in Tokyo, Japan, which was set to expire in November 2024. In April 2024, the Company entered into an agreement to extend the lease for an additional three years through November 2027. In connection with the new lease agreement, the Company recorded an ROU asset and lease liability of \$420,000.

Operating lease cost consisted of the following (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Operating lease cost	\$ 1,266	\$ 1,223	\$ 3,784	\$ 3,664
Variable lease cost	360	362	1,016	1,125
Total lease cost	\$ 1,626	\$ 1,585	\$ 4,800	\$ 4,789

Cash paid for amounts included in the measurement of operating lease liabilities was \$1.4 million and \$1.4 million during the three months ended September 30, 2025 and 2024, respectively, and \$4.2 million and \$4.0 million, during the nine months ended September 30, 2025 and 2024, respectively.

The following table summarizes the maturities of the aggregate lease payments under the Company's operating lease liabilities as of September 30, 2025 (in thousands):

	September 30, 2025
Operating Leases:	
2025	\$ 1,458
2026	5,799
2027	5,186
2028	5,155
2029	5,309
Thereafter	3,646
Total minimum lease payments	26,553
Less: Amount of lease payments representing interest	4,764
Present value of future minimum lease payments	\$ 21,789
Less: current portion	5,523
Operating lease liabilities, net of current portion	\$ 16,266

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The following table summarizes additional information related to the Company's operating leases (in thousands, except weighted-average data):

	September 30, 2025	December 31, 2024
Right-of-use assets	\$ 17,108	\$ 18,805
Weighted-average remaining lease term (years)	4.7	5.5
Weighted-average discount rate	9.1 %	9.0 %

7. Commitments and Contingencies

Royalty Commitments

The Company has entered into various exclusive technology licensing agreements and other software licensing agreements. The terms of the agreements require the Company to make annual royalty payments in fixed amounts as well as certain milestone and revenue-based payments. The revenue-based royalty percentage is in the low single digits, subject to reductions and offsets in certain circumstances with a minimum royalty commitment of \$50,000 annually. Future minimum royalty commitments due under the terms of these exclusive agreements as of September 30, 2025 are as follows (in thousands):

	September 30, 2025
Minimum Royalty Commitments:	
2025	\$ —
2026	50
2027	50
2028	50
2029	50
Thereafter	50
Total minimum royalty commitments	\$ 250

The Company incurred royalty expense of \$586,000 and \$428,000 for the three months ended September 30, 2025 and 2024, respectively, and \$1.5 million and \$1.2 million for the nine months ended September 30, 2025 and 2024, respectively.

Purchase Commitments

Open purchase commitments consist of agreements to purchase goods and services that are entered into in the ordinary course of business. These amounts were not recorded as liabilities on the condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024 as the Company had not yet received the related goods or services. As of September 30, 2025, the Company had estimated open purchase commitments for goods and services of \$4.5 million over the next three years.

Contingencies

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. The Company may pursue or be subject to litigation and other legal actions from time to time arising in the ordinary course of business, including intellectual property, products liability, breach of contract, commercial, employment, and other similar claims which could have an adverse impact on its reputation, business and financial condition and divert the attention of its management from the operation of its business. The Company discloses

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information regarding each material claim where the likelihood of a loss contingency is probable or reasonable possible and accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual or disclosures as of September 30, 2025 and December 31, 2024.

Indemnifications

The Company provides general indemnifications to management and the members of the Company's board of directors (the "Board of Directors") when they act, in good faith, in the best interest of the Company. The Company is unable to develop an estimate of the maximum potential amount of future payments that could potentially result from any hypothetical future claim, but expects the risk of having to make any payments under these general business indemnifications to be remote. The Company also maintains insurance coverage that would generally enable the Company to recover a portion of any future amounts paid.

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8. Term Loan

2024 Credit Agreement

On June 14, 2024, the Company entered into a Credit Agreement and Guaranty (the "2024 Credit Agreement") with Hayfin for a \$138.1 million term loan (the "2024 Term Loan") to refinance its outstanding loan obligations under the 2021 Credit Agreement, as amended (the "2021 Credit Agreement"). In addition, in connection with the 2024 Term Loan, the Company entered into several other adjoining agreements with Hayfin. The 2024 Term Loan extended the maturity date from January 19, 2026 to June 14, 2028. The 2024 Credit Agreement was accounted for as a debt modification for accounting purposes.

On January 24, 2025, in connection with the issuance of the 2025 Convertible Notes, the Company entered into Amendment No. 1 to the 2024 Credit Agreement, in which Hayfin converted \$23.0 million of principal under the 2024 Term Loan to 2025 Convertible Notes under the same terms as the other purchasers of the 2025 Convertible Notes. The amendment was accounted for as a debt modification for accounting purposes.

Prepayment Terms and Other Fees

Any prepayment or repayment of the principal balance of the 2024 Term Loan was subject to an exit fee. The Company accreted the exit fee over the loan term using the effective interest method. Under the 2024 Term Loan, the Company had the option to prepay the 2024 Term Loan subject to a prepayment fee of 1.5% for prepayments after the second anniversary but on or prior to the third anniversary of the 2024 Term Loan and a prepayment fee of 3% for prepayments thereafter. The 2024 Credit Agreement required the Company to repay the loan in full immediately upon the occurrence of a change in control. In addition, immediately upon the consummation of an IPO or SPAC transaction, as defined in the terms of the 2024 Credit Agreement, the Company was required to repay the 2024 Term Loan in an amount equal to the lesser of (i) the net cash proceeds of such IPO or SPAC transaction in excess of \$150.0 million and (ii) \$35.0 million. In connection with Amendment No. 1 to the 2024 Term Loan in January 2025, the amount immediately payable upon the consummation of an IPO or SPAC transaction, as defined in the terms of the 2024 Credit Agreement, was amended where repayment of the 2024 Term Loan was required to be at an amount equal to the lesser of (i) the net cash proceeds of such IPO or SPAC transaction in excess of \$150.0 million and (ii) \$50.0 million (or \$55.0 million if the underwriters exercised any portion of their option to purchase additional shares).

On June 14, 2024, concurrently with entering the 2024 Credit Agreement, the Company signed a fee letter agreement with Hayfin under which the Company agreed to pay \$9.2 million in fees to Hayfin, which consisted of a 3% exit fee and a 3% early prepayment fee due under the 2021 Credit Agreement in the amount of \$8.3 million payable in sixteen equal quarterly installments of approximately \$518,000 through March 31, 2028, agent fees of \$150,000, due in annual installments of \$30,000 through March 31, 2028 and an upfront fee of \$721,000. The Company paid the \$721,000 upfront fee and \$30,000 agent fee upon the closing of the 2024 Term Loan. The exit fee and early prepayment fee was required to be repaid in full immediately upon the occurrence of a financing event, including, but not limited to, any IPO, SPAC transaction, or issuance of convertible notes or equity. The exit fee and early prepayment fee remaining under the original terms of the 2024 Term Loan, which were immediately due and payable upon issuance of the 2025 Convertible Notes, was amended in January 2025 to be immediately due and payable upon the next occurrence of a financing event and was fully repaid on August 18, 2025 upon completion of the Company's IPO as described above.

On August 18, 2025, the Company repaid \$55.0 million of indebtedness outstanding under the 2024 Credit Agreement for which it was obligated in connection with the completion of the Company's IPO and approximately \$5.8 million in fees consisting of a 3% exit fee and a 3% early prepayment fee due under the 2021 Credit Agreement, as amended.

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On August 22, 2025, the Company prepaid in full all outstanding amounts under, and terminated, the 2024 Credit Agreement, in the aggregate principal amount of \$60.1 million plus accrued interest of \$1.0 million. The Company did not incur exit or prepayment fees in connection with the termination of the 2024 Credit Agreement.

Interest

During its term, the 2024 Term Loan bore interest at a floating per annum rate in an amount equal to the sum of (i) 7.0% (or 6.0% if the alternative base rate ("ABR") is in effect) plus (ii) the greater of (x) the forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR") for a respective tenor (or the alternative base rate, if applicable), and (y) 2.0%. The ABR equals the sum of (i) 6.0% plus (ii) the greater of (1) the Wall Street Journal Prime Rate, plus 0.5%, (2) the Federal Reserve Bank of New York rate plus 0.5% or (3) CBA Term SOFR for one month tenor plus 1.0%. The Company had the option to pay interest in-kind at the rate equal to the cash interest rate plus 1.0%.

Debt Issuance Costs and Debt Discount

Debt issuance costs include third-party costs incurred in connection with the original Credit Agreement. Debt discount includes fees paid to the lender, warrants issued to the lender and the embedded derivative liability as described below.

Prior to the refinancing of the 2021 Credit Agreement with the 2024 Term Loan (the "2024 Term Loan Refinancing"), certain prepayment features of the Term Loan, default put option and default interest adjustment features were determined to be embedded derivatives requiring bifurcation and separate accounting for at fair value as a single compound derivative. The fair value of the derivative liability was \$2.1 million, as of the issuance date in January 2021, and was remeasured to fair value at each reporting period. In connection with the 2024 Term Loan Refinancing, the associated current fair value of the derivative liability of \$1.1 million was remeasured at the date of refinancing and was derecognized and recorded as a debt discount to the 2024 Term Loan. Refer to Note 13 for additional information.

In connection with the conversion of \$23.0 million of principal under the 2024 Term Loan to 2025 Convertible Notes under Amendment No.1 to the 2024 Credit Agreement in January 2025, \$239,000 of pro-rata debt discount under the 2024 Term Loan was reclassified as a debt discount under the 2025 Convertible Notes.

Prior to the term loan repayment in August 2025, the debt issuance costs and debt discount were classified as an offset to the Term Loan on the condensed consolidated balance sheets, and was accreted over the loan term using the effective interest method.

Debt Components

The components of the Term Loan are as follows (in thousands):

	December 31, 2024
Principal value of Term Loan	\$ 138,137
Accreted exit fee	567
Debt discount	(2,095)
Debt issuance costs	(178)
Total Term Loan	\$ 136,431

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9. Convertible Notes

2025 Convertible Notes

In January and March 2025, the Company issued convertible promissory notes to Requisite Holders in the aggregate amount of \$98.3 million, which was comprised of \$74.0 million in principal amount of notes issued for cash consideration, \$1.3 million in principal amount of notes issued in lieu of cash compensation to certain employees and \$23.0 million in principal amount of notes issued from the conversion of principal under the 2024 Term Loan. Net cash proceeds was \$72.8 million after deducting \$1.2 million of debt issuance costs.

Prior to its conversion upon the Company's IPO, the 2025 Convertible Notes were due and payable in full 48 months from the issue date and did not accrue interest for one year following the date of issuance. Upon completion of the Company's IPO in August 2025, the 2025 Convertible Notes automatically converted into 6,470,743 shares of the Company's common stock at \$15.20 per share, which was a 20% discount to the IPO price.

Prior to its conversion upon the Company's IPO, the 2025 Convertible Notes contained embedded derivative features, including conversion upon a change in control and automatic conversion upon completion of a qualified IPO, that were required to be bifurcated and accounted for separately as a single derivative instrument. The issuance date estimated fair values of the derivative liability was \$11.1 million and \$20.8 million in January and March 2025, respectively, which was accounted for as a debt discount. See Note 13 for additional information. The debt issuance costs and debt discount were classified as an offset to the 2025 Convertible Notes on the condensed consolidated balance sheets, and were accreted over the loan term using the effective interest method. Upon the closing of the Company's IPO, the remaining unamortized debt discount and debt issuance costs of \$28.8 million were reclassified to additional paid-in capital.

10. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock consisted of the following as of December 31, 2024 (in thousands, except share amounts):

Series	December 31, 2024			
	Number of Shares Authorized	Number of Shares Issued and Outstanding	Carrying Value	Liquidation Value
Series A	4,082,965	4,082,965	\$ 2,041	\$ 2,041
Series B-1	1,954,846	1,954,846	6,940	6,940
Series B-2	2,848,263	2,848,263	10,111	10,111
Series C	11,343,434	11,343,434	104,378	193,167
Series D	7,151,873	7,151,873	110,756	110,854
Series E	12,040,980	12,040,980	304,197	305,018
Series F	61,344,029	61,344,029	168,957	262,295
Series F-1	21,465,064	21,465,064	61,186	61,491
Total	122,231,454	122,231,454	\$ 768,566	\$ 951,917

Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 51,226,348 shares of common stock. Shares of Series A, Series B-1, Series B-2, Series C, Series D, Series E, Series F and Series F-1 outstanding redeemable convertible preferred stock converted into shares of common stock on a 0.342466:1, 0.403088:1, 0.403088:1, 0.576386:1, 0.646673:1, 0.695098:1,

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0.342466:1, and 0.342466:1 basis, as adjusted for the Reverse Stock Split, respectively. As of September 30, 2025, the Company does not have any convertible preferred stock issued or outstanding.

11. Stockholders' Equity

Preferred Stock

At September 30, 2025, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 50,000,000 shares of preferred stock with \$0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At September 30, 2025, under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue 250,000,000 shares of \$0.001 par value common stock, of which 83,473,696 shares were issued and outstanding. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of September 30, 2025, no dividends have been declared to date. Each share of common stock is entitled to one vote.

Common stock reserved for future issuance, on an as-converted basis, consisted of the following:

	September 30, 2025	December 31, 2024
Redeemable convertible preferred stock	—	51,226,348
Options to purchase common stock	10,006,820	8,537,203
Restricted stock units	813,283	—
Shares reserved for issuance under the Company's equity plans	15,639,547	370,902
Common stock warrants	1,647,667	1,647,667
Total	28,107,317	61,782,120

12. Common Stock Warrant Liability

On January 19, 2021, in connection with entering into the Credit Agreement, the Company issued Hayfin a warrant to purchase 108,154 shares of common stock at an exercise price of \$0.03 per share. On March 17, 2022, upon amendment to the Credit Agreement, the Company issued Hayfin a warrant to purchase 77,253 shares of common stock at an exercise price of \$0.03 per share. On March 3, 2023, upon Amendment No. 4 to the Credit Agreement and as a result of antidilution adjustment provisions in connection with the Series F redeemable convertible preferred stock financing, the Company issued Hayfin a warrant to purchase 1,462,260 shares of common stock at an exercise price of \$0.03 per share (collectively, the "Warrants"). As of September 30, 2025 and December 31, 2024, all warrants remained outstanding.

The Warrants have a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the Company's stock at the time of exercise of the Warrants after deduction of the aggregate

exercise price. The Warrants also have customary antidilution protection provisions. The Warrants are scheduled to terminate on the ten-year anniversary of the issuance date, however, the Warrants are scheduled to automatically net exercise immediately prior to termination if the fair market value of one share of common stock exceeds the then current exercise price per share of common stock. In connection with certain change of control transactions, which include SPAC combinations, mergers, consolidations and the sale or lease of substantially all of the assets of the Company, the Warrants automatically net exercise if the fair market value of one share of common stock exceeds the then current

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exercise price per share of common stock. The Warrants do not automatically net exercise in connection with an IPO.

The aggregate fair value of the Warrants issued in connection with the 2021 Credit Agreement and the amended 2021 Credit Agreement was \$4.3 million and \$3.5 million, respectively, at issuance and was recognized as a debt discount and recorded as a warrant liability.

The warrant liabilities were remeasured to fair value, resulting in a loss of \$32.1 million and \$585,000 during the three months ended September 30, 2025 and 2024, respectively, and a loss of \$34.6 million and \$4.5 million during the nine months ended September 30, 2025 and 2024, respectively, within the condensed consolidated statements of operations and comprehensive loss.

At September 30, 2025 and December 31, 2024, the fair value of the common stock warrant liability was determined using the Black-Scholes option pricing model based on the following weighted average assumptions:

	September 30, 2025	December 31, 2024
Stock price	\$ 33.66	\$ 12.68
Exercise price	\$ 0.03	\$ 0.03
Contractual term (in years)	5.8	6.6
Expected volatility	55.7 %	72.1 %
Weighted-average risk-free interest rate	3.80 %	4.44 %
Dividend yield	0 %	0 %

See Note 18 for information about the common stock warrant exercise.

13. Derivative Liability

Term Loan

Prior to the 2024 Term Loan Refinancing in June 2024, the Term Loan contained certain prepayment features, default put option and default interest adjustment features that were determined to be embedded derivatives requiring bifurcation and separate accounting as a single compound derivative, as discussed in Note 8. The fair value of the derivative liability was recorded at the issuance date as debt discounts and reductions to the carrying value of long-term debt on the condensed consolidated balance sheets. The derivative liability is remeasured to fair value at each reporting period, and the related changes in fair value are recorded on the condensed consolidated statements of operations and comprehensive loss. Through the time of the 2024 Term Loan Refinancing in June 2024, the Company continued to adjust the derivative liability for changes in fair value of the Term Loan.

Estimating fair values of the derivative liability requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Since the derivative financial instrument is initially and subsequently carried at fair value, the Company's income will reflect the volatility in these estimate and assumption changes.

The derivative liability was remeasured to fair value as of June 14, 2024, resulting in a loss of \$222,000 within the condensed consolidated statements of operations and comprehensive loss. In connection with the 2024 Term Loan Refinancing on June 14, 2024, the associated current fair value of the derivative liability of \$1.1 million as remeasured at the date of refinancing was derecognized and recorded as a debt discount to the 2024 Term Loan.

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The fair value of the derivative liability was estimated using a scenario-based analysis comparing the probability-weighted present value of the Term Loan payoff at maturity with and without the bifurcated features. The Company used both the Black-Scholes-Merton and option pricing method to estimate the fair value of the derivative liability because it believes these techniques are reflective of all significant assumption types and ranges of assumption inputs that market participants would likely consider in transactions involving compound embedded derivatives. The option pricing method was employed as part of a back-solve analysis to the Company's Series F Preferred round of financing. The Company's

assumptions used in determining the fair value of the derivative liability is as follows:

	June 14, 2024
Debt yield	18.5 %
Probability of business combination or IPO (with feature)	80.0 %
Event date of business combination or IPO (with feature)	6/30/2025
Probability of Default	5.0 %
Event date of Default	9/30/2025
Probability to incur new debt	0.0 %
Event date to incur new debt	n/a
Probability of change of control	10.0 %
Event date of change of control	6/30/2025
Event date (without feature)	1/19/2026

Debt yield — Discount rate that reconciles the total fair value of the Warrants and 2021 Credit Agreement with the transaction value. Debt yield reflects a change in the credit benchmark for a “CCC” rated obligation.

2025 Convertible Notes

The 2025 Convertible Notes were determined to contain certain settlement features and conversion put options which require bifurcation and separate accounting as a single compound embedded derivative, as discussed in Note 9. The fair value of the derivative liability was recorded at the issuance dates as a debt discount and reduction to the carrying value of the 2025 Convertible Notes on the condensed consolidated balance sheets. The derivative liability is remeasured to fair value at each reporting period and the related changes in fair value are recorded on the condensed consolidated statements of operations and comprehensive loss.

The fair value of the derivative liability was estimated using a scenario-based analysis comparing the probability-weighted present value of the 2025 Convertible Notes with and without the bifurcated features. The Company used the Monte Carlo Simulation method to estimate the fair value of the derivative liability because it believes this technique is reflective of all significant assumption types and ranges of assumption inputs that market participants would likely consider in transactions involving compound embedded derivatives. The option pricing method was employed as part of a back-solve analysis for scenarios in which the Company was expected to raise another financing round. The Company also employed a waterfall analysis that allocated certain exit proceeds to its outstanding share classes for

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scenarios in which the Company was assumed to exit via change of control or IPO. The Company’s assumptions used in determining the issuance date fair value of the derivative liability is as follows:

	January 31, 2025	March 26, 2025
Debt yield	7.0 %	7.0 %
Probability of IPO	60.0 %	75.0 %
Event date of IPO	5/5/2025	5/9/2025
Probability of change of control	20.0 %	10.0 %
Event date of change of control	1/31/2026	3/26/2026
Discount rate	31.3 %	63.7 %

The issuance date estimated fair values of the derivative liability was \$11.1 million and \$20.8 million in January and March 2025, respectively, which were recorded as debt discounts. The derivative liability was remeasured to fair value at the end of each reporting period and through the date of its conversion to common stock upon the Company’s IPO, resulting in a gain of \$4.8 million and \$7.3 million for the three and nine months ended September 30, 2025, respectively, within the condensed consolidated statements of operations and comprehensive loss. The aggregate estimated fair value of the derivative liability at the time of conversion was \$24.6 million, based on the 20% discount from the IPO price, which was reclassified to additional paid-in capital.

14. Stock-Based Compensation Plans

In 2009, the Company adopted its 2009 Equity Incentive Plan which provided for the grant of stock options to the Company’s employees, members of the Board of Directors and consultants. Effective upon the Company’s IPO in August 2025, the Company’s Board of Directors approved the termination of the 2009 Equity Incentive Plan and the adoption of the 2025 Performance Incentive Plan (“2025 Plan”). Options granted under the 2025 Plan may be either incentive stock options (“ISOs”) or nonqualified stock options (“NSOs”). ISOs may be granted only to employees. NSOs, Stock Appreciation Rights, Restricted Stock, and Restricted Stock Units (“RSUs”) may be granted to employees, members of the Board of Directors and consultants. A total of 17,189,139 shares of common stock were initially reserved for issuance pursuant to the 2025 Plan. In addition, the shares reserved for issuance under the 2025 Plan will also include shares reserved but not issued under the 2009 Equity Incentive Plan, plus any share awards granted under the 2009 Equity Incentive Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2025 Plan will also include an annual increase on the first day of each fiscal year

beginning in fiscal 2026, equal to or greater than (i) 5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year less any Board of Directors approved increase(s) during the preceding fiscal year; or (ii) an amount as determined by the Board of Directors.

Options under the 2009 Equity Incentive Plan and 2025 Plan have a term of ten years from the grant date. The option exercise price will be determined by the Board of Directors, but will be no less than 100% of the fair market value per share on the date of grant. In addition, in the case of an ISO granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock of the Company, the per share exercise price will be no less than 110% of the fair market value per share on the date of grant. Through September 30, 2025 and December 31, 2024, options granted generally vest over (i) four years with 25% vesting on the first anniversary of the issuance date and 1/48th per month thereafter or (ii) vesting monthly in equal installments over four years.

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Stock option activity under the Company's 2009 Equity Incentive Plan and 2025 Plan is set forth below (in thousands, except share and per share amounts):

	Number of Options	Awards Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024	8,537,210	\$ 4.72	7.96	\$ 68,256
Options granted	2,317,260	\$ 17.79		
Options exercised	(487,890)	\$ 4.98		
Options canceled	(359,760)	\$ 6.24		
Balance at September 30, 2025	<u>10,006,820</u>	\$ 7.68	8.01	\$ 260,007
Vested and exercisable, September 30, 2025	3,892,199	\$ 5.24	6.70	\$ 110,604
Vested and expected to vest, September 30, 2025	10,006,820	\$ 7.68	8.01	\$ 260,007

The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2025 was \$10.84 and \$10.12 per share, respectively.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at each reporting period. The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2025 was \$4.8 million and \$6.9 million, respectively.

Restricted Stock Units

In August 2025, the Company began granting RSUs under the 2025 Plan. RSUs generally vest over four years in equal quarterly increments. The fair value of RSUs is based on the Company's closing stock price on the date of grant. A summary of RSUs activity is set forth below:

	Number of Restricted Stock Units	Awards Weighted- Average Grant Date Fair Value
Unvested at December 31, 2024	—	\$ —
Awards granted	822,386	\$ 19.14
Awards vested	—	—
Awards canceled	(9,103)	\$ 19.00
Unvested at September 30, 2025	<u>813,283</u>	\$ 19.14

2025 Employee Stock Purchase Plan

In August 2025, the Company's Board of Directors adopted the 2025 Employee Stock Purchase Plan ("2025 ESPP") to be effective upon the Company's IPO, under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total of 1,233,964 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, beginning in 2026, by an amount equal to the lesser of (i) 1.0% of the issued and outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (ii) an amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2025 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the "IRC").

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Heartflow, Inc.
Notes to Condensed Consolidated Financial Statements
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Stock-Based Compensation

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model based on the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2025	2024	2025	2024	
Expected life (in years)	6.0	5.6	6.0	5.6	
Expected volatility	56.6%-57.9%	54.5%-54.6%	55.0%-57.9%	53.7%-54.6%	
Risk-free interest rate	3.7%-3.9%	3.5 %	3.7%-4.2%	3.5%-4.4%	
Dividend yield	– %	– %	– %	– %	

The Company estimated the fair value of the shares to be issued under the Company's 2025 ESPP using the Black-Scholes option-pricing model based on the following assumptions:

	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025	
	Expected life (in years)	0.6	
Expected volatility	58.1 %	58.1 %	
Risk-free interest rate	4.1 %	4.1 %	
Dividend yield	– %	– %	

The significant assumptions used in these calculations are summarized as follows:

Fair value of common stock. Because there had been no public market for the Company's common stock prior to the IPO, the fair value of common stock shares underlying stock options has historically been determined by the Board of Directors at the time of option grant by considering an independent valuation performed by a third-party valuation firm as well as a number of objective and subjective factors, including a valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, among other factors. The fair value of common stock was determined in accordance with applicable elements of the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Subsequent to its IPO, the fair value of the underlying common stock is based on the closing price of the Company's common stock on the Nasdaq Stock Market on the date of grant.

Expected term. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company does not have sufficient historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term of options and has opted to use the "simplified method," whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected volatility. As the Company was not publicly traded prior to the IPO and does not have sufficient trading history after the IPO, the expected volatility for the Company's stock options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to the Company's business corresponding to the expected term of the awards.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities corresponding to the expected term of the awards.

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Heartflow, Inc.

Notes to Condensed Consolidated Financial Statements

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Expected dividend yield. The expected dividend rate is zero as the Company currently has no history or expectation of declaring dividends on its common stock.

The Company also issues stock options with vesting based upon completion of performance goals. The fair value for these performance-based awards is recognized over the period during which the goals are to be achieved. Stock-based compensation expense recognized at fair value includes the impact of estimated probability that the goals would be achieved, which is assessed prior to the requisite service period for the specific goals.

Total stock-based compensation expense is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2025	2024	2025	2024	
Cost of revenue	\$ 127	\$ 71	\$ 229	\$ 231	
Research and development	959	563	1,887	1,566	
Selling, general and administrative	2,874	1,702	6,589	5,902	
Total stock-based compensation expense	\$ 3,960	\$ 2,336	\$ 8,705	\$ 7,699	

As of September 30, 2025, total unrecognized stock-based compensation costs related to unvested stock options was \$31.1 million, which is expected to be recognized over a remaining weighted-average period of 3.23 years, a total of \$15.0 million of unrecognized compensation costs related to unvested RSUs expected to be recognized over a period of approximately 3.91 years and \$1.3 million of unrecognized compensation costs related to the ESPP, which the Company will recognize over 0.44 years.

15. Employee Retirement Plan

The Company has a qualified retirement plan under section 401(k) of the IRC under which participants may contribute up to 100% of their eligible compensation, subject to maximum deferral limits specified by

the IRC. The Company may make matching contributions of up to 4.0% of an employee's eligible compensation, subject to conditions specified by the IRC. The Company's matching contributions totaled \$297,000 and \$377,000 during the three months ended September 30, 2025 and 2024, respectively, and \$1.8 million and \$1.4 million during the nine months ended September 30, 2025 and 2024, respectively.

16. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	\$ (50,855)	\$ (19,140)	\$ (92,396)	\$ (63,451)
Denominator:				
Weighted-average shares used to compute net loss per share, basic and diluted	49,106,752	5,586,424	20,686,526	5,185,007
Net loss per share, basic and diluted	\$ (1.04)	\$ (3.43)	\$ (4.47)	\$ (12.24)

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Heartflow, Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the period presented because including them would have been antidilutive:

	September 30,	
	2025	2024
Redeemable convertible preferred stock	—	122,231,454
Outstanding options to purchase common stock	10,006,820	8,009,198
Restricted stock units	813,283	—
Estimated ESPP	231,558	—
Common stock warrants	1,647,667	1,647,667
Total	12,699,328	131,888,319

17. Income Taxes

The Company had an effective tax rate of 0% for both the three and nine months ended September 30, 2025 and 2024. The Company continues to incur operating losses.

During the three and nine months ended September 30, 2025 and 2024, the Company has evaluated all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income, and has determined that it is more likely than not that its net deferred tax assets will not be realized. Due to uncertainties surrounding the realization of the deferred tax assets, the Company continues to maintain a full valuation allowance against its net deferred tax assets.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBA") was signed into law in the United States which contains a broad range of tax reform provisions affecting businesses. The provisions of the OBBA did not have a material impact on the Company's condensed consolidated financial statements for the three and nine months ended September 30, 2025.

18. Subsequent Events

For the interim condensed consolidated financial statements as of September 30, 2025, and for the three and nine months then ended, the Company has evaluated events through the date the unaudited interim condensed consolidated financial statements were available to be issued.

2025 Facility Lease

On July 2, 2025, the Company entered into a facility lease agreement for approximately 8,100 rentable square feet of office space in San Francisco, California for 39 months through November 30, 2028, with the option to extend for one additional three-year period. In connection with the lease, the Company paid a security deposit of \$90,000. The average monthly lease payments are approximately \$40,000 per month during the lease term. The lease commenced on November 1, 2025.

Hayfin Common Stock Warrants Exercise

On October 22, 2025, Hayfin net exercised all common stock warrants outstanding for 1,646,317 shares of common stock. The common stock warrant liability was remeasured to fair value through the date of exercise, with the related change of approximately \$9.3 million being reflected as a change in fair value of common stock warrant liability on the consolidated statements of operations and comprehensive loss. The final fair value of \$64.7 million will be reclassified to stockholders equity (deficit).

Heartflow, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Civil Investigative Demand Investigation

In October 2025, the Company and certain of its employees received civil investigative demands (the "CID") from the U.S. Department of Justice, Civil Division, in connection with an investigation under the federal Anti-Kickback Statute and Civil False Claims Act (the "Investigation"). The CID requests information, documents, and testimony focused on the Company's financial and contractual arrangements with providers and its sales and marketing activities. The Company is cooperating with the Investigation and is unable to express a view at this time regarding the likely duration, or ultimate outcome, of the Investigation or estimate the possibility of, or amount or range of, any possible financial impact. Depending on the outcome of the Investigation, there may be a material impact on the Company's business, results of operations, financial condition, or cash flows.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2024 included in our registration statement on Form S-1 (File No. 333-288733), which became effective on August 7, 2025. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Part II, Item 1A, "Risk factors" and elsewhere in this Quarterly Report on Form 10-Q. Please also see the section titled "Special Note Regarding Forward-looking Statements." Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We have pioneered the use of software and artificial intelligence ("AI") to deliver a more accurate and clinically effective non-invasive solution for diagnosing and managing coronary artery disease ("CAD"), a leading cause of death worldwide. As of September 30, 2025, our Heartflow Platform has been used to

assess CAD in more than 500,000 patients, including 132,000 in 2024 alone. We believe that we are the most widely adopted AI-powered test for CAD. Our novel platform leverages AI and advanced computational fluid dynamics to create a personalized 3D model of a patient's heart from a single coronary computed tomography angiography ("CCTA"), a specialized type of scan that provides detailed images of the heart's arteries. Our Heartflow Platform delivers actionable insights on blood flow, stenosis, plaque volume and plaque composition thereby overcoming the limitations of traditional non-invasive imaging tests which rely on indirect measures of coronary disease and lead to higher false negative and false positive rates as demonstrated by our PRECISE trial. We believe the differentiated accuracy and clinical utility of our Heartflow Platform, along with its ability to enhance workflows, will continue to support our growth and advance the "CCTA + Heartflow" pathway as the definitive standard for the non-invasive diagnosis and management of CAD.

To date, we have developed three software products (with a fourth product expected to launch in 2026) under the Heartflow Platform that provide physicians with the critical insights needed to effectively diagnose and manage CAD:

- *Heartflow RoadMap Analysis* offers a highly intuitive anatomic visualization of the coronary arteries, helping physicians quickly identify clinically relevant areas to focus their review. We provide Heartflow RoadMap Analysis to accounts as an integrated feature to enhance the efficiency of their CCTA program, and it is not a stand-alone product.
- *Heartflow FFR_{CT} Analysis* calculates blood flow and pinpoints clinically significant CAD, which is CAD with a fractional flow reserve ("FFR") value of 0.80 or below, at every point in the major coronary arteries. FFR measures the severity of blood flow restriction in the coronary arteries on a scale of 1.0 (no restriction) to 0.0 (complete blockage) by assessing pressure differences across a stenosis during induced stress, guiding decisions on whether a patient requires invasive revascularization.
- *Heartflow Plaque Analysis* provides a comprehensive assessment of coronary plaque, enabling optimized medical treatment strategies.

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- *Heartflow PCI Planner*, which we expect to launch in 2026, will provide advanced visualization and clinical insights to optimize revascularization strategies, guide device selection, enhance procedural efficiency, and improve patient care. We plan to provide Heartflow PCI Planner to accounts as an integrated feature to enhance procedural efficiency, not as a stand-alone product.

The Heartflow Platform has an existing commercial presence and regulatory approval in the United States, United Kingdom, European Union, Australia, Canada and Japan. We have developed a highly scalable, capital efficient commercial model that combines Territory Sales Managers who drive new account adoption with Territory Account Managers who focus on increasing utilization by educating referring physicians. Our commercial team does not cover cases or otherwise spend time in an operating room or lab setting, which enables them to focus solely on driving commercial adoption and educational activities. We also have small, direct commercial teams in our international markets. In the future, we may expand our international presence beyond these markets.

Our technology is simple and intuitive and does not require the purchase of any capital equipment. Our onboarding process seamlessly integrates the Heartflow Platform into the customer's daily workflow. These unique attributes of our business model afford our commercial organization a differentiated level of efficiency and scalability.

We have experienced considerable revenue growth since we began commercializing the Heartflow Platform in 2015, driven primarily by growth in our account base and increasing test volumes at accounts in our installed base. For the three months ended September 30, 2025 and 2024, we recognized revenue of \$46.3 million and \$32.9 million, respectively, and for the nine months ended September 30, 2025 and 2024, we recognized revenue of \$126.9 million and \$90.8 million, respectively. Substantially all of our revenue is generated on a "pay-per-click" basis each time a physician chooses to review either our Heartflow FFR_{CT} Analysis, Heartflow Plaque Analysis, or both, and we recognize usage-driven fee revenue upon delivery of the requested analysis to the physician. Heartflow FFR_{CT} Analysis has served as our commercial foundation, representing 98% of our total revenue as of September 30, 2025. In the second half of 2023, we initiated limited market education efforts for Heartflow Plaque Analysis, our second commercial product, and we expect to broaden our market education efforts as payor coverage for Heartflow Plaque Analysis increases. Heartflow Plaque Analysis is currently covered by certain government and third-party payors. Our Heartflow RoadMap Analysis is generally provided as a workflow efficiency tool to drive customer retention and loyalty and is not a stand-alone product.

Prior to our initial public offering ("IPO"), we primarily funded our operations with proceeds from sales of shares of our redeemable convertible preferred stock, common stock and convertible promissory notes, borrowings under our term loans and revenue received from our customers. As of September 30, 2025, we had \$291.2 million in cash and cash equivalents. In January and March 2025, we issued \$98.3 million in aggregate principal amount of the 2025 Convertible Notes to investors, including related parties, with original maturity dates of 48 months from the dates of issuance. The consideration for the issuance of the 2025 Convertible Notes was comprised of \$74.0 million in cash, \$1.3 million in aggregate principal amount of notes issued in lieu of cash compensation to certain employees, and the exchange of \$23.0 million of outstanding indebtedness under the 2024 Credit Agreement (as defined below).

On August 11, 2025, we completed our IPO, in which we issued and sold 19,166,667 shares of our common stock, which includes an additional 2,500,000 shares of common stock purchased by the underwriters pursuant to their option to purchase additional shares, at a price to the public of \$19.00 per share. The cash proceeds from our IPO were approximately \$332.3 million, net of underwriting discounts and commissions and estimated offering costs of \$31.8 million. Additionally, upon the closing of our IPO, the aggregate outstanding principal balance of \$98.3 million under the 2025 Convertible Notes automatically converted into 6,470,743 shares of our common stock at \$15.20 per share, a 20% discount from our IPO price.

We have incurred significant operating losses and negative cash flows since our inception, and we expect to continue to incur losses as we grow and transition to now operating as a public company. As of September 30, 2025, we had an accumulated deficit of \$1.1 billion.

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Key Factors Affecting Our Results of Operations and Performance

We believe there are several important factors that have impacted and that we expect will continue to impact our operating performance and results of operations for the foreseeable future. These factors include, among others:

- Rate of adoption of CCTA in the market and our ability to increase adoption of the CCTA+ Heartflow pathway among both referring and reading physicians.
- Ability to successfully introduce our Heartflow Plaque Analysis and other new products and the rate at which they are adopted by physicians.
- Ability to automate an increasing number of the manual components of our production process and the rate at which we hire and train analysts to full productivity.
- Seasonality we experience throughout the year, including due to staff availability, vacations, weather and other macro economic events.
- Publications of clinical results by us and third parties.

Heartflow Revenue Cases

We regularly review a number of operating and financial metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. Substantially all of our revenue is generated on a “pay-per-click” basis each time a physician chooses to review either our Heartflow FFR_{CT} Analysis, Heartflow Plaque Analysis, or both, and we recognize usage-driven fee revenue upon delivery of the requested analysis to the physician. We define a “Heartflow revenue case” as each time an account orders and we deliver the requested analysis to the physician. For example, the ordering of both an Heartflow FFR_{CT} Analysis and a Heartflow Plaque Analysis from a single CCTA counts as two revenue cases. We define an “account” as any individual facility that orders a Heartflow FFR_{CT} Analysis, Heartflow Plaque Analysis, or both. Accounts may have more than one reading physician or CT machine. The following table lists these revenue cases in each of the three month periods as indicated:

	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025
Revenue cases	19,537	21,769	23,195	24,897	28,803	33,039	34,970	37,805	40,336	48,423	51,805

The period-to-period change in Heartflow revenue cases is an indicator of our ability to drive adoption and generate sales revenue, and is helpful in tracking the progress of our business. We believe that Heartflow revenue cases are representative of our current business; however, we anticipate this metric may be substituted for additional or different metrics as our business grows.

Components of Our Results of Operations

Revenue

Substantially all of our revenue comprises usage-driven fees from accounts who order either our Heartflow FFR_{CT} Analysis or our Heartflow Plaque Analysis, or both. We recognize usage-driven fee revenue upon delivery of the requested analysis to the physician. Key factors that drive our revenue include revenue case growth from our installed base and the success of our sales force in expanding adoption of the Heartflow Platform to new accounts and expanding the utilization of our system by accounts in our installed base. We consider an account that has our Heartflow solution deployed with the ability to send us CCTA images for processing as being part of our installed base. New accounts generally take 12 months to reach steady state revenue case volumes. We consider steady state case volumes to be attained once the account reaches FFR_{CT} utilization rates approaching 33% of CCTAs occurring at the account—a level that is generally sustained over time based on historical trends. Our Heartflow FFR_{CT} Analysis is indicated for patients with stenosis levels between 40% and 90%, and we

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believe approximately 33% of patients have this level of stenosis. For purposes of managing our business, we do not separately track increases in revenue solely attributable to new accounts. Revenue cases generated from clinic or office-based accounts typically carry a lower pricing than hospital-based accounts, commensurate with their lower reimbursement levels. We expect the percentage of our revenue cases generated from clinic or office-based accounts to continue to increase over time. The percentage of our U.S. revenue cases attributable to office and clinic-based accounts was 32% and 29% for the three months ended September 30, 2025 and 2024, respectively, and 31% and 28% for the nine months ended September 30, 2025 and 2024, respectively.

While a single customer may include multiple accounts, no single customer accounted for 10% or more of our revenue during the three and nine months ended September 30, 2025 and 2024. However, the decision-making function for some 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 our accounts. For example, for the year ended December 31, 2024, our top two largest customers, both large health systems with multiple accounts, collectively represented approximately 8% of our revenue. As we expand the adoption of the Heartflow Platform, we expect a majority of new accounts to come from new customers, decreasing our customer concentration risk.

Our revenue has fluctuated, and we expect it to continue to fluctuate from quarter-to-quarter due to a variety of factors including the number of accounts in our installed base, the volume of Heartflow Platform usage by accounts in our installed base, customer pricing contracts that include utilization and volume rebates, changes in the mix of customer accounts and seasonality. We may experience fluctuations in the volume of Heartflow Platform usage by our customers based on seasonal factors that impact the number of radiologists and support staff available to conduct CCTAs at customer accounts.

Cost of revenue and gross margin

Cost of revenue consists of personnel and related expenses, including stock-based compensation costs, primarily related to our production team. Additional costs include third-party hosting fees, amortization of capitalized internal-use software, amortization of contract fulfillment costs as well as royalties associated with technology licenses used in connection with the delivery of our product and allocated overhead, which includes facilities expenses, equipment, depreciation and technology services. These costs are partially offset by capitalized contract fulfillment costs. The role of the production team is to support our patient case volume revenue by performing defined quality-related activities on CCTA scans submitted by our customers for analysis. The portion of these costs that supports patient case volume revenue is recorded as cost of revenue. The production team also supports activities in our clinical trials and research and development, which are allocated as research and development expense. We expect cost of revenue to increase as we hire additional personnel in our production team to support our increasing patient case volume.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our production team costs, the timing of hiring new production team members and training them to full productivity, the timing of our acquisition of new customers and the related capitalization of contract fulfillment costs, and the pricing and commercialization of Heartflow Plaque Analysis and other new products. Although, we expect our gross margin to fluctuate from period to period, based upon the factors described above, we believe our gross margin will increase over the long term as we leverage the AI-based nature of our software platform to automate an increasing number of the manual components of our production team's process, thereby lowering the cost of revenue per analysis. We also expect increased revenues from our Heartflow Plaque Analysis to positively impact our gross margin, as it runs on the same CCTA scan as Heartflow FFR_{CT} Analysis. In the short term, we expect modulations in our gross margin as we hire and train additional personnel in our production team to support our increasing patient case volume. These expenses are offset by the varying levels of support provided by the production team in our clinical trials and research and development, which are allocated as research and development expense, and the capitalization of contract fulfillment costs.

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Operating expenses

Research and development

Research and development expenses are incurred in connection with the advancement of the Heartflow Platform with the goal to introduce products, features and improvements aimed at increasing the value proposition for our customers by expanding its applicability to additional disease states and patient populations. Research and development expenses consist primarily of engineering, product development, consulting services, clinical studies to develop and support our products, regulatory activities, medical affairs, and other costs associated with products and technologies that are in development. Research and development expenses consist of personnel and related expenses, including stock-based compensation costs, clinical trials, third-party consulting costs, the portion of the costs incurred by our production team to support clinical trials and research and development efforts, and allocated overhead, including facilities expenses, equipment and depreciation. Our research and development team is comprised of PhD research scientists with expertise in AI-based algorithms and medical imaging, alongside software engineers skilled in cloud architecture, AI algorithms, machine and deep learning and 3D visualization, as well as product managers and designers who ensure optimal customer experience and design. We record research and development expenses in the periods in which they are incurred. We expect our research and development expenses to increase as we conduct clinical studies for expanded indications for use and to hire additional personnel to develop new product offerings and product enhancements.

Selling, general and administrative

Selling, general and administrative expenses consist of personnel and related expenses, including stock-based compensation costs, related to selling and marketing, commercial operations, reimbursement, finance, legal, information technology and human resources functions. Other expenses include sales commission, marketing initiatives, professional service fees (including legal, audit, accounting and tax fees), market access work to secure reimbursement for our technologies, travel expenses, conferences and trade shows, and allocated overhead, which includes facilities expenses, software licenses, depreciation and other miscellaneous expenses.

We expect that our selling, general and administrative expenses will increase in the future as a result of expanding our operations, including hiring personnel, to both drive and support anticipated growth as well as various incremental costs associated with operating as a public company. We expect that our costs will increase related to legal, audit, accounting fees, consulting fees, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs and other expenses that we did not incur as a private company. However, we expect selling, general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Interest expense, net

Interest expense, net consisted primarily of interest expense on our 2024 Term Loan and related amortization of debt discount and debt issuance costs. Interest income is primarily interest earned on our cash and cash equivalents.

Other income (expense), net

Other income (expense), net consists primarily of changes in fair value related to our common stock

warrant and derivative liability, loss on extinguishment of debt, as well as foreign exchange transaction gains or losses from transactions and asset and liability balances denominated in currencies other than the U.S. dollar. We will continue to record adjustments to the estimated fair value of the common stock warrant liability until the warrants are exercised and we continued to record adjustments to the estimated fair value of the derivative liability until their conversion upon our IPO. All of our common stock warrants were net exercised in October 2025.

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Provision for income taxes

Provision for income taxes consists of income tax expense in foreign jurisdictions. To date, we have not recorded any U.S. federal or state income tax expense. We have net deferred tax assets for U.S. federal income taxes for which we provide a full valuation allowance. Due to our history of net operating losses since inception, we expect to maintain a full valuation allowance in the foreseeable future due to uncertainties regarding our ability to realize these assets.

Results of Operations

Comparison of Three Months Ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024:

(dollars in thousands)	Three Months Ended		Change	
	2025	2024	\$	%
Revenue	\$ 46,276	\$ 32,934	\$ 13,342	41%
Cost of revenue	10,861	7,997	2,864	36%
Gross profit	35,415	24,937	10,478	42%
Operating expenses:				
Research and development	17,297	11,863	5,434	46%
Selling, general and administrative	33,217	28,003	5,214	19%
Total operating expenses	50,514	39,866	10,648	27%
Loss from operations	(15,099)	(14,929)	(170)	1%
Interest expense, net	(1,726)	(4,478)	2,752	-61%
Other income (expense), net	(34,000)	267	(34,267)	*
Loss before provision for income taxes	(50,825)	(19,140)	(31,685)	166%
Provision for income taxes	(30)	—	(30)	*
Net loss	\$ (50,855)	\$ (19,140)	\$ (31,715)	166%

*: Not Meaningful

Revenue

Revenue increased \$13.3 million, or 41%, to \$46.3 million during the three months ended September 30, 2025, compared to \$32.9 million during the three months ended September 30, 2024. The increase in revenue was primarily attributable to a 48% increase in revenue case volume, partially offset by a reduction in average sales price due to a higher percentage of revenue cases generated from clinic and office-based accounts and an increase in utilization and volume rebates.

Cost of revenue and gross margin

Cost of revenue increased \$2.9 million, or 36%, to \$10.9 million during the three months ended September 30, 2025, compared to \$8.0 million during the three months ended September 30, 2024. This increase was primarily attributable to an increase of \$2.2 million in personnel and related expenses, \$0.3 million in third-party hosting fees, \$0.2 million in royalties, and \$0.1 million in computer hardware expenses. Personnel and related expenses included \$127,000 and \$71,000 of stock-based compensation costs during the three months ended September 30, 2025 and 2024, respectively. Gross margin for the three months ended September 30, 2025 increased to 77% as compared to 76% for the three months ended September 30, 2024. The increase in our gross margin for the three months ended September 30, 2025 was primarily attributable to our increase in revenue case volume and improved production team productivity partially offset by our continued investment in the hiring and training of additional personnel in our production team to support our increasing revenue case volume. Although we expect to continue to

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invest in the hiring and training of additional personnel in our production team, we expect our gross margin will continue to increase over the longer term.

Research and development expenses

Research and development expenses increased \$5.4 million, or 46%, to \$17.3 million during the three months ended September 30, 2025, compared to \$11.9 million during the three months ended September 30, 2024. The increase in research and development expenses was primarily attributable to an increase of \$3.6 million in personnel and related expenses directly associated with an increase in headcount, \$0.7 million in consulting and professional fees, \$0.4 million in allocated production team costs to support

clinical trials and research and development efforts, \$0.3 million in software-related costs, \$0.2 million in third-party hosting fees and \$0.1 million in allocated overhead. Personnel and related expenses included \$1.0 million and \$0.6 million of stock-based compensation costs during the three months ended September 30, 2025 and 2024, respectively.

Selling, general and administrative expenses

Selling, general and administrative expenses increased \$5.2 million, or 19%, to \$33.2 million during the three months ended September 30, 2025, compared to \$28.0 million during the three months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily attributable to an increase of \$4.4 million in personnel and related expenses directly associated with an increase in headcount, \$0.5 million in computer hardware and software-related costs, \$0.5 million in advertising and other promotional expenses, \$0.4 million in travel expenses, partially offset by a decrease of \$0.3 million in allocated overhead, \$0.2 million in professional fees, including legal, audit and consulting fees, and \$0.2 million in capitalized commissions and implementation costs. Personnel and related expenses included \$2.9 million and \$1.7 million of stock-based compensation costs for the three months ended September 30, 2025 and 2024, respectively.

Interest expense, net

Interest expense, net decreased to an expense of \$1.7 million during the three months ended September 30, 2025, compared to an expense of \$4.5 million during the three months ended September 30, 2024. This decreased expense was mainly attributable to the repayment in full of our 2024 Term Loan in August 2025 and the conversion of our 2025 Convertible Notes to common stock upon IPO in August 2025.

Other income (expense), net

Other income (expense), net increased to an expense of \$34.0 million during the three months ended September 30, 2025, compared to an income of \$0.3 million during the three months ended September 30, 2024. The increase was primarily attributable to a \$32.1 million charge from the remeasurement and recognition of the change in fair value related to our common stock warrant liability and a \$6.4 million loss on extinguishment of debt related to the full repayment of our 2024 Term Loan in August 2025, partially offset by a \$4.8 million benefit from the remeasurement and recognition of the change in fair value related to our derivative liability during the three months ended September 30, 2025.

Provision for income taxes

Provision for income taxes was \$30,000 for the three months ended September 30, 2025, compared to \$0 for the three months ended September 30, 2024, which was related to our state and foreign taxes.

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Comparison of Nine Months Ended September 30, 2025 and 2024

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024:

(dollars in thousands)	Nine Months Ended September 30,		Change	
	2025	2024	\$	%
Revenue	\$ 126,904	\$ 90,831	\$ 36,073	40%
Cost of revenue	30,770	22,632	8,138	36%
Gross profit	96,134	68,199	27,935	41%
Operating expenses:				
Research and development	46,253	31,238	15,015	48%
Selling, general and administrative	96,197	82,125	14,072	17%
Total operating expenses	142,450	113,363	29,087	26%
Loss from operations	(46,316)	(45,164)	(1,152)	3%
Interest expense, net	(12,262)	(14,142)	1,880	-13%
Other income (expense), net	(33,729)	(4,097)	(29,632)	*
Loss before provision for income taxes	(92,307)	(63,403)	(28,904)	46%
Provision for income taxes	(89)	(48)	(41)	85%
Net loss	\$ (92,396)	\$ (63,451)	\$ (28,945)	46%

*: Not Meaningful

Revenue

Revenue increased \$36.1 million, or 40%, to \$126.9 million during the nine months ended September 30, 2025, compared to \$90.8 million during the nine months ended September 30, 2024. The increase in revenue was primarily attributable to a 45% increase in revenue case volume, partially offset by a reduction in average sales price due to a higher percentage of revenue cases generated from clinic and office-based accounts and an increase in utilization and volume rebates.

Cost of revenue and gross margin

Cost of revenue increased \$8.1 million, or 36%, to \$30.8 million during the nine months ended September 30, 2025, compared to \$22.6 million during the nine months ended September 30, 2024. This increase was primarily attributable to \$4.8 million in personnel and related expenses, \$1.0 million in allocated overhead, \$0.6 million in third-party hosting fees, \$0.5 million in amortization of capitalized internal-use software, \$0.5 million in computer hardware expenses and \$0.3 million in royalties, partially offset by

production team support costs allocated to research and development expense. Personnel and related expenses included \$0.2 million and \$0.2 million of stock-based compensation costs during the nine months ended September 30, 2025 and 2024, respectively. Gross margin for the nine months ended September 30, 2025 increased to 76% as compared to 75% for the nine months ended September 30, 2024. The increase in our gross margin for the nine months ended September 30, 2025, was primarily attributable to our increase in revenue case volume and improved production team productivity, partially offset by our continued investment in the hiring and training of additional personnel in our production team to support our increasing revenue case volume.

Research and development expenses

Research and development expenses increased \$15.0 million, or 48%, to \$46.3 million during the nine months ended September 30, 2025, compared to \$31.2 million during the nine months ended September 30, 2024. The increase in research and development expenses was primarily attributable to an increase of \$9.4 million in personnel and related expenses directly associated with an increase in headcount,

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\$1.7 million in clinical trial expenses, \$1.6 million in consulting and professional fees, \$0.6 million in software-related costs, \$0.5 million of capitalized internal-use software costs, \$0.5 million in third-party hosting fees, \$0.3 million in grant expense and \$0.3 million in allocated production team costs to support clinical trials and research and development efforts. Personnel and related expenses included \$1.9 million and \$1.6 million of stock-based compensation costs during the nine months ended September 30, 2025 and 2024, respectively.

Selling, general and administrative expenses

Selling, general and administrative expenses increased \$14.1 million, or 17%, to \$96.2 million during the nine months ended September 30, 2025, compared to \$82.1 million during the nine months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily attributable to an increase of \$9.8 million in personnel and related expenses directly associated with an increase in headcount, \$2.5 million in professional fees, including legal, audit and consulting fees, \$1.7 million in marketing expenses, \$1.3 million in computer hardware and software-related costs and \$0.7 million in travel costs, partially offset by a decrease of \$1.2 million of capitalized commission costs and \$1.2 million in facilities costs and allocated overhead. Personnel and related expenses included \$6.6 million and \$5.9 million of stock-based compensation costs for the nine months ended September 30, 2025 and 2024, respectively.

Interest expense, net

Interest expense, net decreased to an expense of \$12.3 million during the nine months ended September 30, 2025, compared to an expense of \$14.1 million during the nine months ended September 30, 2024. This decreased expense was primarily attributable to a lower aggregate outstanding principal balance under our 2024 Term Loan related to the conversion of \$23.0 million in principal to convertible notes in January 2025 and the full repayment of our 2024 Term Loan in August 2025, partially offset by amortization of debt issuance costs and debt discount related to our 2024 Term Loan and 2025 Convertible Notes through its conversion to common stock upon our IPO in August 2025.

Other income (expense), net

Other income (expense), net increased to expense of \$33.7 million during the nine months ended September 30, 2025, compared to an expense of \$4.1 million during the nine months ended September 30, 2024. The increase was primarily attributable to the remeasurement and recognition of the change in fair value related to our common stock warrant liability charge of \$34.6 million and a loss on extinguishment of debt of \$6.4 million related to the full repayment of our 2024 Term Loan in August 2025, partially offset by a benefit on the remeasurement and recognition of the change in fair value related to our derivative liability of \$7.3 million.

Provision for income taxes

Provision for income taxes was \$89,000 and \$48,000 for the nine months ended September 30, 2025 and 2024, respectively, related to our state and foreign taxes.

Liquidity and Capital Resources

Sources of liquidity

As of September 30, 2025, we had \$291.2 million in cash and cash equivalents and an accumulated deficit of \$1.1 billion. Prior to our IPO, we primarily funded our operations with proceeds from sales of shares of our redeemable convertible preferred stock, common stock and convertible promissory notes, borrowings under our term loans and revenue received from our customers, which we expect to be our primary source of future liquidity.

We expect to continue to incur losses and to expend significant amounts of cash in the foreseeable future as we continue to scale our business, invest in research and development activities, increase sales and

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marketing efforts to support commercial expansion, and increase general and administrative expenses to support being a publicly-traded company.

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the expected cash generated from revenue transactions with customers, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months.

Hayfin credit agreement

On June 14, 2024, we entered into a Credit Agreement and Guaranty for a \$138.1 million term loan to refinance the outstanding obligations under the initial credit agreement we entered into with Hayfin on January 19, 2021 and the additional term loans entered into with Hayfin on March 17, 2022 in exchange for the payment of exit fees and early prepayment fees in the aggregate amount of \$8.3 million payable in sixteen equal quarterly installments, or immediately upon the occurrence of our IPO. On January 24, 2025, in connection with the issuance of the 2025 Convertible Notes as further described below, we entered into Amendment No. 1 to the Credit Agreement and Guaranty (as amended, the "2024 Credit Agreement") to amend the terms and conditions governing the term loan outstanding thereunder (as amended, the "2024 Term Loan"). Under this amendment, Hayfin also converted \$23.0 million of principal under the 2024 Term Loan to 2025 Convertible Notes under the same terms as the other purchasers of the 2025 Convertible Notes.

The 2024 Term Loan was scheduled to mature on June 14, 2028 and bore interest equal to the sum of (i) 7.0% (or 6.0% if the alternative base rate ("ABR") was in effect) plus (ii) the greater of (x) the forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR") for a respective tenor in effect on such day (or the alternative base rate, if applicable), and (y) 2.0%. The ABR equaled the sum of (i) 6.0% plus (ii) the greater of (1) the Wall Street Journal Prime Rate, plus 0.5%, (2) the Federal Reserve Bank of New York rate plus 0.5% or (3) the CBA Term SOFR for one month tenor plus 1.0%. We had an option to pay interest in-kind at the rate equal to the cash interest rate plus 1.0% through the last interest period ending before the 18th month anniversary of the 2024 Credit Agreement. We had an option to prepay the 2024 Term Loan subject to a prepayment fee of 1.5% for prepayments after the second anniversary but on or prior to the third anniversary of the 2024 Term Loan and a prepayment fee of 3% for prepayments thereafter.

On August 18, 2025, we repaid \$55.0 million of indebtedness outstanding under the 2024 Credit Agreement for which we were obligated to pay in connection with the completion of our IPO and approximately \$5.8 million in fees consisting of a 3.0% exit fee and a 3.0% early prepayment fee due under the 2021 Credit Agreement, as amended.

On August 22, 2025, we prepaid in full all outstanding amounts under, and terminated, the 2024 Credit Agreement, in the aggregate principal amount of \$60.1 million plus accrued interest of \$1.0 million. We did not incur exit or prepayment fees in connection with the termination of the 2024 Credit Agreement.

Convertible notes

In January and March 2025, we issued convertible promissory notes to various investors and certain employees in the aggregate amount of \$98.3 million, which was comprised of \$74.0 million in aggregate principal amount of notes issued for cash consideration, \$1.3 million in aggregate principal amount of notes issued in lieu of cash compensation to certain employees and \$23.0 million in aggregate principal amount of notes issued from the conversion of principal under the 2024 Term Loan Conversion (collectively, the "2025 Convertible Notes"). The 2025 Convertible Notes did not accrue interest for one year following the date of issuance and were due and payable in full 48 months from the issue date. Upon the completion of our IPO, the aggregate outstanding principal balance under the 2025 Convertible Notes automatically converted into shares of our common stock at a 20% discount to the IPO price.

The 2025 Convertible Notes contained embedded derivative features, including conversion upon a change in control and automatic conversion upon completion of a qualified IPO, that were required to be bifurcated and accounted for separately as a single derivative instrument. The issuance date estimated

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fair values of the derivative liability was \$11.1 million and \$20.8 million in January and March 2025, respectively, which were recorded as debt discounts. The derivative liability was remeasured to an aggregate fair value of \$24.6 million immediately before the conversion of the 2025 Convertible Notes to common stock upon the IPO, resulting in a gain of \$7.3 million recorded within the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2025.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

(in thousands)	Nine Months Ended	
	September 30,	
	2025	2024
Net cash used in operating activities	\$ (43,427)	\$ (54,963)
Net cash used in investing activities	(3,126)	(4,025)
Net cash provided by financing activities	286,093	1,386

Net cash used in operating activities

Net cash used in operating activities during the nine months ended September 30, 2025 was \$43.4 million, attributable to a net loss of \$92.4 million and a net change in operating assets and liabilities of \$6.0 million, partially offset by non-cash charges of \$54.9 million. The non-cash charges primarily consisted of \$8.7 million in stock-based compensation expense, \$7.3 million of change in fair value of derivative liability, \$34.6 million of change in fair value of common stock warrant liability, \$4.1 million of depreciation and amortization, \$2.3 million of amortization of right-of-use asset, \$1.1 million of non-cash interest charges, \$5.4 million of amortization of debt discount and debt issuance costs, \$6.4 million of loss on extinguishment of debt and \$0.2 million change in allowance for credit losses. The increase in net operating assets was primarily due to an increase of \$3.0 million in accounts receivable, a \$2.6 million increase in prepaid expenses and other current assets, a \$2.7 million increase in other non-current assets, a \$6.0 million increase in accrued expenses and other current liabilities, a \$0.9 million decrease in accounts payable, and a \$2.7 million decrease in operating lease liabilities.

Net cash used in operating activities during the nine months ended September 30, 2024 was \$55.0 million, attributable to a net loss of \$63.5 million and a net change in operating assets and liabilities of \$12.3 million, partially offset by non-cash charges of \$20.8 million. The non-cash charges primarily consisted of \$7.7 million in stock-based compensation expense, \$3.8 million of depreciation and amortization, \$2.0 million of amortization of right-of-use asset, \$1.5 million of amortization of debt discount and debt issuance costs, \$1.1 million of non-cash interest charges, \$4.5 million of change in fair value of common stock warrant liability and \$0.2 million of change in fair value of derivative liability. The increase in net operating assets was primarily due to a \$2.6 million increase in accounts receivable, a \$1.4 million increase in prepaid expenses and other current assets, a \$1.4 million increase in other non-current assets, a \$1.6 million decrease in accounts payable, a decrease of \$2.7 million in accrued expenses and other current liabilities, and a \$2.4 million decrease in operating lease liabilities.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2025 was \$3.1 million consisting of purchases of property and equipment.

Net cash used in investing activities for the nine months ended September 30, 2024 was \$4.0 million consisting of purchases of property and equipment.

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Net cash provided by financing activities

Net cash provided by financing activities during the nine months ended September 30, 2025 was \$286.1 million, consisting primarily of \$332.8 million in net proceeds from our IPO, \$72.8 million in net proceeds from the issuance of our 2025 Convertible Notes and \$2.4 million in proceeds from the exercise of stock options, offset by \$115.1 million principal repayment under our 2024 Term Loan and \$6.8 million in exit and prepayment penalty fees related to our 2024 Term Loan.

Net cash provided by financing activities during the nine months ended September 30, 2024 was \$1.4 million, consisting primarily of \$3.2 million in proceeds from the exercise of stock options, offset by \$1.8 million in exit and prepayment penalty fees related to our 2024 Term Loan.

Contractual Obligations and Commitments

Our contractual commitments will have an impact on our future liquidity. These commitments include future payments on non-cancellable facility leases, purchase obligations related to research and development and professional services under non-cancellable contracts and royalty obligations for exclusive technology licensing agreements. Upon the closing of our IPO in August 2025, the aggregate outstanding principal balance under the 2025 Convertible Notes automatically converted into shares of our common stock. In August 2025, we repaid \$55.0 million of indebtedness outstanding under the 2024 Term Loan for which we were obligated to pay in connection with the completion of our IPO and subsequently prepaid in full the remaining outstanding principal balance of \$60.1 million. There have been no other material changes to our contractual obligations from those described in our registration statement on Form S-1 (File No. 333-288733), which became effective on August 7, 2025.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about our significant accounting policies and estimates used in the preparation of our condensed consolidated financial statements. There have been no significant and material changes in our critical accounting policies during the three and nine months ended September 30, 2025, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2024 included in our registration statement on Form S-1 (File No. 333-288733), which became effective on August 7, 2025.

Off-balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging Growth Company Status

We are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), which permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of the extended transition period. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements applicable to public companies. The JOBS Act also exempts us from having to provide an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the completion of our IPO; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities, credit risk, foreign currency exchange rate sensitivity and inflation risk.

Interest rate risk

As of September 30, 2025, we had cash and cash equivalents of \$291.2 million. Our cash and cash equivalents are held for working capital purposes. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our cash equivalents, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Our exposures to market risk for changes in interest rates related primarily to our 2024 Term Loan (described above) which bore floating interest rates and a rising interest rate environment would increase the amount of interest paid on these loans. Each 100 basis point increase in these initial rates would increase annual interest expense by approximately \$1.2 million assuming the 2024 Term Loan remained outstanding for the annual period. On August 22, 2025, we prepaid in full all outstanding amounts under the 2024 Term Loan and terminated the 2024 Credit Agreement.

Credit risk

Our cash and cash equivalents, which at times may exceed federally insured limits, is maintained with large financial institutions. As of the issuance date of the financial statements included in this report, we have not experienced any losses on our deposits and all of our cash deposits have been accessible to us.

Our accounts receivable primarily relate to revenue from the sale of our products to medical providers. No customer represented 10% or more of our accounts receivable as of September 30, 2025 and December 31, 2024.

Foreign currency exchange risk

The vast majority of our cash generated from revenue is denominated in U.S. dollars, with a small amount denominated in other foreign currencies. Our expenses are generally denominated in the currencies of the jurisdictions in which we conduct our operations, which are primarily in the United States, United Kingdom and Japan. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have had a material impact on our condensed consolidated financial statements during any of the periods presented. As the impact of foreign currency exchange rates has not been material to our historical operating results, we have not entered into

derivative or hedging transactions, but we may do so in the future if our exposure to foreign currency becomes more significant.

Effects of inflation

Inflation generally affects us by increasing our cost of labor and overhead costs. We do not believe that inflation has had a material impact on our business, results of operations, or financial condition, or on our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of September 30, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until the filing of our Annual Report on Form 10-K for the year ended December 31, 2026. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal

control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that our management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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Part II. Other Information

Item 1. Legal Proceedings

In October 2025, we and certain of our employees received civil investigative demands (the "CID") from the U.S. Department of Justice, Civil Division, in connection with an investigation under the federal Anti-Kickback Statute and Civil False Claims Act (the "Investigation"). The CID requests information, documents, and testimony focused on our financial and contractual arrangements with providers and our sales and marketing activities. We are cooperating with the Investigation. We are unable to express a view at this time regarding the likely duration, or ultimate outcome, of the Investigation. Depending on the outcome of the Investigation, there may be a material impact on our business, results of operations, financial condition, or cash flows.

In addition, we have become, and we may become in the future, involved in various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation for which the outcome, based on our reasonable belief, if determined adversely to us, would individually or taken together, materially and adversely affect our business, financial condition, or results of operations. However, we may from time to time be involved in various claims and legal proceedings of a nature we believe are normal and incidental to a business such as ours. These matters may include employment, contract, intellectual property, product liability and other general claims. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are not material may also impair our business, financial condition, results of operations and prospects. Please also see the sections titled "Special Note Regarding Forward-looking Statements."

Risk Factors Summary

The following risks and uncertainties included in this subsection are among the most significant we face and are qualified in their entirety by reference to all of the risk factors as further described in this Item 1A.

- We have incurred significant net losses since our inception, we expect to incur additional substantial losses in the foreseeable future and we may not be able to achieve or sustain profitability.
- Our revenue is currently generated almost entirely from the sales of only one product, Heartflow FFR_{CT} Analysis, and we are therefore highly dependent on the success of this product, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and any growth.
- If healthcare providers are unwilling to change their standard practice regarding the evaluation of CAD, our business, financial condition, results of operations and prospects will be adversely affected.
- If third-party payors, including government payors, do not cover and provide adequate reimbursement for the Heartflow Platform, or if existing payment amounts are reduced or coding policies change, adoption of the Heartflow Platform by healthcare providers may be negatively impacted, and our business, financial condition, results of operations and prospects will be adversely affected.
- We face risks associated with a concentrated customer base.

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- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may develop products that are more effective, accurate, reliable, cost-effective or more advanced than ours, which may harm our financial condition. If we are unable to compete successfully or our potential market share is reduced, we may be unable to increase or sustain our revenue or achieve profitability.
- The commercialization of Heartflow Plaque Analysis is nascent, and we may not be able to achieve or maintain sufficient market acceptance or the levels of utilization we expect from Heartflow Plaque Analysis or any other future product.
- We face risks associated with our use and development of AI models, which may result in operational challenges, legal liability, reputational concerns and competitive risks.
- If we fail to properly manage our future growth, our business could suffer.
- Our business could be disrupted by catastrophic events.
- We depend on our information technology systems, and any failure of these systems could harm our business and adversely affect our business and operating results.
- Our networks and those of our third-party service providers may become the target of bad actors or security breaches that we cannot anticipate or successfully defend, which could have an adverse impact on our business.
- We face extensive regulatory requirements to bring our products to market, and our failure to receive and maintain regulatory clearances or approvals of our current and future products in the United States or abroad or to comply with medical device regulatory requirements could adversely affect our business.
- If we are unable to obtain and maintain sufficient intellectual property rights, or the scope of our rights is not sufficiently broad, third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Risks Related to our Business and Industry

We have incurred significant net losses since our inception, we expect to incur additional substantial losses in the foreseeable future and we may not be able to achieve or sustain profitability.

We have incurred significant net losses since our inception in 2007, and we expect to incur additional substantial losses in the foreseeable future. For the three and nine months ended September 30, 2025, we incurred net losses of \$50.9 million and \$92.4 million, respectively. As of September 30, 2025, we had an accumulated deficit of approximately \$1.1 billion. Since inception, we have spent significant amounts of cash to develop the Heartflow Platform, to fund research and development, including our preclinical research and development activities and clinical trials related to our products, to scale our commercial operations and to recruit and retain key talent.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. We expect to continue to incur significant research and development, sales and marketing, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials to extend applicability of our platform into new indications or to develop new products or add new features to our existing products. The investments in our business may be more costly than we expect, and if we do not achieve the benefits anticipated from these investments, or if the realization of these benefits is delayed, they may not result in increased revenue or growth in our business. In addition to the anticipated costs of growing our business, we expect

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our general and administrative expenses to increase due to the additional costs of being a public company. If our revenue growth does not increase to more than offset the anticipated increases in our operating expenses, we may not be able to achieve or sustain profitability and our business, financial condition, results of operations and prospects will be harmed.

In addition, our revenue may decline or our revenue growth, if any, may be constrained. Our ability to increase sales is uncertain, and we may never be able to achieve or sustain profitability for many reasons, including that: our Heartflow FFR_{CT} Analysis may not achieve widespread adoption among healthcare providers and we may be unable to increase revenue generated from sales of our Heartflow FFR_{CT} Analysis; our Heartflow Plaque Analysis may not achieve widespread adoption among healthcare providers and we may be unable to generate sufficient revenue from sales of our Heartflow Plaque Analysis; payors, such as insurance companies and government insurance programs, may decide not to reimburse for our products, may set the amount of such reimbursement too low or may reduce the amount of such reimbursement; healthcare industry trends, including growth in CCTA usage, may move in directions that do not allow for adoption of our products or that do not provide adequate incentives for the adoption of our products; competitors may develop or acquire a product that successfully competes with ours; manufacturers of CT scanners may partner with our competitors or develop or acquire a competing

product and integrate one or more products that successfully competes with ours; we may not be able to obtain regulatory approval for future versions of our products (including improved versions of our AI algorithms), new indications for use of our products or other future products; and there may be changes in existing or anticipated clinical guidelines, including the current American College of Cardiology ("ACC") and American Heart Association ("AHA") Class 1, Level A guidelines for CCTA and Class 2a, Level B guidelines for Heartflow FFR_{CT} Analysis for certain patients with stable or acute chest pain and no known CAD, or the timing of adoption of positive clinical guidelines that support the use of the Heartflow FFR_{CT} Analysis.

Because of these and the other risks and uncertainties described in this Quarterly Report on Form 10-Q, we are unable to predict the extent to which we will be able to increase sales, if at all, or the timing for when or the extent to which we will become profitable, if ever. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would depress the value of our company and our stock price and could impair our ability to raise capital, fund our research and development efforts, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Our revenue is currently generated almost entirely from the sales of only one product, Heartflow FFR_{CT} Analysis, and we are therefore highly dependent on the success of this product, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and any growth.

As of September 30, 2025, our Heartflow FFR_{CT} Analysis represented 98% of our total revenue. In the second half of 2023, we began limited market education efforts of our second product, Heartflow Plaque Analysis. Over the next several years, we expect to continue to devote a substantial amount of resources to increase sales of our Heartflow FFR_{CT} Analysis and also expand our commercialization efforts and drive increased adoption of our Heartflow Plaque Analysis. However, we may not succeed in increasing sales of our Heartflow FFR_{CT} Analysis or in increasing adoption of our Heartflow Plaque Analysis. We expect to continue to derive almost all of our revenue from sales of Heartflow FFR_{CT} Analysis for the foreseeable future, so we are highly dependent on its success.

In addition, because we plan to devote substantial resources to increase sales of Heartflow FFR_{CT} Analysis and rely on it as our main source of revenue, any factors that negatively impact these efforts, our Heartflow Plaque Analysis commercialization efforts or our ability to diversify our products would have a material adverse effect on our business, financial condition, results of operations and prospects.

Therefore, it is difficult to predict our future prospects and forecast our financial performance and any growth, and any such forecasts are inherently limited and subject to a number of uncertainties. If our

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assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business, financial condition, results of operations and prospects could suffer.

If healthcare providers are unwilling to change their standard practice regarding the evaluation of CAD, our business, financial condition, results of operations and prospects will be adversely affected.

Our success depends on physicians, hospitals and other healthcare providers adopting and using the Heartflow Platform to aid in the evaluation of CAD. While we have had some recent success in achieving broader adoption of the Heartflow Platform, we have in the past faced, and may in the future face, challenges in achieving higher rates of adoption. Many healthcare providers have extensive experience with existing non-invasive tests for CAD and have established relationships with the companies that provide these tests or in some instances own or manage the equipment for these tests in their offices. Existing tests are performed in a high enough volume that healthcare providers generate sufficient revenue from their use and are well versed in their use, reimbursement and outcomes. The outcomes and workflow efficiencies that we believe our Heartflow Platform provides may not be valued by healthcare providers as highly as we expect or at all. In addition, healthcare providers have been, and may continue to be, slower to adopt or recommend our products because we have a more limited commercial track record and healthcare providers may feel they can generate more revenue from existing tests. Healthcare providers also may not find our clinical data compelling and may not recommend or use our products until they receive additional recommendations from other healthcare providers that our products have a clinical benefit, or at all.

In addition, the Heartflow Platform relies on healthcare providers following the ACC and AHA guidelines by referring certain patients with stable or acute chest pain and no known CAD to undergo a CCTA, with the CCTA images to be analyzed by our Heartflow FFR_{CT} Analysis. Although the ACC and AHA guidelines support CCTA plus our Heartflow FFR_{CT} Analysis as the preferred pathway for diagnosing and managing CAD in certain patients with stable or acute chest pain and no known CAD, these guidelines may not be widely adopted by healthcare providers. Moreover, healthcare providers may choose not to adopt the Heartflow Platform if they are not able to obtain an adequate CCTA. Further, if future studies and trials or other events, including reimbursement rates of CCTA, adversely impact the rate of use of CCTAs in practice, then healthcare providers may be less willing to adopt a technology that uses CCTAs.

Also, the Heartflow Platform may be more difficult than we expect to integrate into standard practice because a provider may be resistant to introduce our embedded information technology and workflow infrastructure. Due to different laws, policies and preferences of healthcare providers regarding patient privacy both in the United States and abroad, they may be averse to sending data externally (outside of their facility) or abroad. Furthermore, if healthcare providers using the Heartflow Platform experience what they perceive to be false negative result or imprecise readings, including due to user error, they may determine not to continue using our platform going forward.

We expect that addressing these and similar issues will require a significant amount of our time and resources, and if we are unsuccessful, we would be unable to achieve broader adoption of the Heartflow Platform by healthcare providers. If our products do not gain broader acceptance by healthcare providers, our business, financial condition, results of operations and prospects will be adversely affected.

If third-party payors, including government payors, deny coverage or provide inadequate reimbursement for our Heartflow Platform, or existing payors cover and provide adequate reimbursement for our Heartflow Platform but existing payors' coverage or reimbursement policies change, adoption of the Heartflow Platform by healthcare providers may be negatively impacted, and our business, financial condition, results of operations and prospects will be adversely affected.

Our ability to grow sales and revenue from our Heartflow FFR_{CT} Analysis and to successfully commercialize our Heartflow Plaque Analysis depend, in large part, on whether third-party payors,

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including private health insurers, managed care plans and government healthcare programs, such as Medicare and Medicaid, cover and adequately reimburse for the use of the Heartflow Platform and the underlying CCTA. Patients generally rely on payors to reimburse all or a significant part of the costs associated with their treatment. As a result, appropriate coding, coverage determinations, and reimbursement levels are critical to the commercial success of the Heartflow Platform. Reimbursement is obtained from a variety of sources, including government sponsored and private health insurance plans, and varies by country and by region within some countries. These payors determine whether to provide coverage and payment for specific products and procedures.

In addition, payors continually review new technologies and can, without notice, change coverage parameters, deny coverage, bundle services, or reduce payment amounts. As a result, the coverage determination process is often time consuming and costly, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. If payors change their reimbursement policies, or if the current Category I CPT codes related to our Heartflow FFR_{CT} Analysis or future Category I CPT codes related to our Heartflow Plaque Analysis are not favorably categorized or priced, reimbursement for the Heartflow Platform could be reduced to an amount that would make adoption of our Heartflow Platform challenging.

Moreover, physicians, hospitals and other healthcare providers may decline to adopt or reduce usage of the Heartflow Platform due to the economic impact a negative change in reimbursement may have on their business and, as a result, we may experience a significant loss of revenue, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Reimbursement for our Heartflow Platform, which includes the separately billable services, Heartflow FFR_{CT} Analysis and Heartflow Plaque Analysis, is subject to periodic changes to reimbursement levels by government payors and private health insurers. For example, the Centers for Medicare and Medicaid Services ("CMS") adopts changes to reimbursement policies during the annual Medicare rulemaking process, which includes updates to Medicare payment levels to hospitals under the Medicare Hospital Outpatient Prospective Payment System ("OPPS") rule, and updates to Medicare payment rates to physician offices, independent diagnostic testing facilities, and freestanding imaging centers under the Medicare Physician Fee Schedule ("MPFS") rule. In addition to risks associated with government reimbursement, our Heartflow FFR_{CT} Analysis and Heartflow Plaque Analysis technologies face reimbursement uncertainty from commercial payors, such as UnitedHealthcare, Aetna, Cigna, Anthem, and regional Blue Cross Blue Shield plans. Such commercial payors routinely reassess their medical policies, coverage criteria and payment policies and rates, and may choose to deny coverage or payment, impose restrictive utilization management protocols (such as prior authorization), or reduce or bundle payment amounts based on internal cost-effectiveness assessments or evolving clinical guidelines. Even if Medicare maintains favorable reimbursement, commercial payors may independently determine whether Heartflow FFR_{CT} Analysis or Heartflow Plaque Analysis meets their plans' medical necessity standards, which may vary among commercial payors.

As part of their participation in the Medicare program and in support of the annual rulemaking process, hospitals submit Medicare cost reports and report their charges for specific services provided in the hospital setting. These cost and charge data reported from hospitals can impact reimbursement rates because CMS uses that data to determine future Medicare reimbursement levels on an annual basis. In the aggregate, when costs associated with a specific service reported by the hospitals decrease, there is a risk that CMS will reduce the reimbursement rate proportionately. These lower reported costs can be a result of coding errors or erroneous denials of claims, the inclusion of lower-cost services within the APC, reductions in costs for services within the APC, or other similar issues. For example, in July 2025, CMS issued the proposed 2026 OPPS rule, which, if finalized as proposed, could result in a reduction of up to 15% in the Medicare reimbursement rate for the clinical APC that includes our Heartflow FFR_{CT} Analysis, along with other hospital services. CMS publishes final OPPS and MPFS rules in the fourth quarter each year. We cannot be sure at this time whether the proposed hospital reimbursement rate for Heartflow FFR_{CT} Analysis for 2026 will be finalized, modified, or if CMS will increase the rate back to 2025 levels. There is a risk that similar or other coding or claims issues may occur and lead CMS to lower the

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reimbursement rate for the Heartflow Platform for 2027 or in future years. In addition, we may not become aware of any such issues early enough to prevent any adverse impacts to the reimbursement for our products, and our ability to remedy any such issues may be limited by applicable laws, regulations or policies.

Given the evolving nature of the healthcare industry and ongoing healthcare cost reforms, we are and will continue to be subject to effects of changes in the level of reimbursement for our products. We cannot be sure that third-party payors will maintain the current level of coverage and payment to our customers for use of our existing products. A reduction in coverage or payment or change in policy by the Medicare program could cause some commercial third-party payors to implement similar reductions in their

coverage or payment amounts for the Heartflow Platform. Unfavorable coverage or payment determinations at the national or local level could adversely affect our business, financial condition, results of operations and prospects.

We face risks associated with a concentrated customer base.

Our Heartflow Platform had an installed base of more than 1,100 accounts in the United States as of December 31, 2024. We define an “account” as any individual facility that orders a Heartflow FFR_{CT} Analysis, Heartflow Plaque Analysis, or both. We define an account as “new” if a unique facility begins generating revenue cases for our FFR_{CT} Analysis, Plaque Analysis, or both. Accounts may have more than one reading physician or CT machine. Conversely, a “customer” can be either an individual account or a health or hospital system with multiple accounts. While a single customer may include multiple accounts, no single customer accounted for 10% or more of our revenue during the three and nine months ended September 30, 2025 and 2024. However, the decision-making function for some 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 our accounts. For example, for the year ended December 31, 2024, our top two largest customers, both large health systems with multiple accounts, collectively represented approximately 8% of our revenue.

We cannot guarantee that we will continue to generate revenue from these customers, whether due to an increase in competition, new technologies, our customers’ ability to terminate their contracts with us or reduce order volumes, or other factors outside of our control. If we do not increase the number of our customers and drive increased use of the Heartflow Platform as the preferred non-invasive testing method for assessing CAD, we will continue to face risks associated with a more concentrated customer base.

Revenue from these customers may fluctuate from time to time due to demand for the Heartflow Platform, the timing of which may be affected by seasonality or other factors outside of our control such as CT scanner capacity, contrast availability and staffing availability. These customers could also potentially pressure us to reduce the prices we charge for the Heartflow Platform, which could have a material adverse effect on our margins and business. For example, during the year ended December 31, 2024, our average sales price was impacted by customer pricing contracts that included utilization and volume rebates and by changes in the mix of customer accounts, which is a trend we expect to continue in the near term, and it is possible that similar trends in customer pricing contracts may continue to have a negative impact on our average sales price in the future. In addition, if any of our largest customers terminates its relationship with us or otherwise reduces its FFR_{CT} Analysis volumes for any reason, we may be unable to replace them with a customer who refers a similar number of patients for the Heartflow Platform, and such termination or reduction in volume could have a material adverse effect on our business, financial condition, results of operations and prospects.

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We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may develop products that are more effective, accurate, reliable, cost-effective or more advanced than ours, which may harm our financial condition. If we are unable to compete successfully or our potential market share is reduced, we may be unable to increase or sustain our revenue or achieve profitability.

The medical technology industry is highly competitive, subject to rapid change and significantly affected by the introduction of new products and technologies and other activities of industry participants. Because of the size of the market opportunity for the treatment of CAD, we believe current and potential future competitors will dedicate significant resources to aggressively promote their products or develop new products or treatments. Our principal competition comes from companies that provide traditional non-invasive tests that aid physicians in the evaluation of CAD, such as SPECT, stress echocardiography and PET. Established, traditional non-invasive tests for CAD have been used for many years and are therefore difficult to change or supplement. Many of the companies that sell these traditional non-invasive tests or the equipment they require have established relationships with healthcare providers. One of the major hurdles to adoption of our products is overcoming established testing patterns, which requires education of physicians and supportive clinical data.

The companies that sell the traditional non-invasive tests for CAD include companies that offer: (i) cardiac specific tests to primary care and cardiology offices, such as manufacturers of capital equipment for stress echocardiography and SPECT, including GE Healthcare, Siemens Healthineers AG and Koninklijke Philips N.V.; and (ii) products used for the invasive FFR testing market.

With the greater resources of some of these competitors and their more diversified product offerings, it is possible that they or other entrants into the market may develop competing products or technologies that could be more effective, accurate, reliable, cost-effective, more advanced or otherwise improved relative to the Heartflow Platform, which could render our products obsolete or less competitive. In addition, one or more competitors could develop and market an on-premise solution, which may be more appealing than our cloud-based offering. Moreover, new treatments, such as GLP-1s, may indirectly reduce stenosis or plaque build-up, which could reduce the market opportunity for non-invasive CAD tests and, as a result, our Heartflow Platform. In addition, we currently target our Heartflow Platform for use only on symptomatic patients and expanding the Heartflow Platform for asymptomatic patients may take years, with potential delays due to the high-risk nature of the effort. Our competitors who offer traditional non-invasive tests offer those tests to both symptomatic and asymptomatic patients, and this increased market penetration could create additional price pressure for our products.

In addition, the field of cardiovascular genomics is subject to rapidly changing technology, and others may invent and commercialize technology platforms such as next generation sequencing approaches that could compete with our products or could make our products or any product we may sell in the future obsolete. We also face competition and price pressure from companies that have developed or are

developing AI-based platforms that leverage CCTA to diagnose CAD, including earlier-stage companies such as Cleerly, Inc., Evidic Bioimaging Inc. and Keya Medical Technology Co., Ltd. We may also face competition from companies developing AI-based platforms, even if they are not currently in the CAD market and recent and future advances in AI may allow other companies to quickly create competing products, and they may be able to create such products less expensively and benefit from FDA and reimbursement approvals we and others have obtained. For us to remain competitive, we must continuously work on our products' design and features, improve our algorithms, and invest in and develop new technologies, including in the rapidly evolving area of AI. If we are unable to introduce products, features and improvements aimed at increasing the value proposition of the Heartflow Platform for our customers, or if the products, features and improvements we introduce are viewed less favorably than our competitors' products, we may be unable to compete successfully. If we are unable to compete successfully against our current or future competitors, we may be unable to increase market acceptance for our products, which could prevent us from increasing or sustaining our revenue or achieving profitability and could cause the market price of our common stock to decline.

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In addition, the Heartflow Platform relies on a CCTA first being performed, as the Heartflow Platform requires a CT image from a CT scanner to perform its analysis. A number of companies manufacture CT scanners, including, among others, GE Healthcare, Hitachi, Ltd., Koninklijke Philips N.V., Samsung Electronics Co., Ltd., Siemens Healthineers AG and Canon Medical Systems Corporation. These companies are more diversified than we are and have substantial financial, manufacturing, sales and marketing distribution and other resources. Any of these companies or others could determine to develop, partner with or acquire and offer a product that competes with ours or manufacture CT scanners that are no longer compatible with our Heartflow Platform. Further, these larger companies have market penetration in the CT scanner market and understand the market for CAD and, if they are able to develop, partner with or acquire a competing product, they may offer it as a bundle with the purchase of a CT scanner, which could prevent us from increasing or sustaining our revenue or achieving profitability. In the past, three of these companies, Siemens Healthineers AG, Koninklijke Philips N.V. and Canon Medical Systems Corporation, considered development of a local workstation-based technology prototype aimed at deriving CT-based blood flow data without an invasive procedure. If these companies decide to further pursue this technology and obtain regulatory approval or clinical validation, it may become competitive with our products. In addition, we are reliant on these third-party CCTAs and CT scanners continuing to support standard output file formats that our Heartflow Platform supports. If a CT manufacturer were to change to a proprietary format or develop a novel method of performing CT scans, we would need to further develop our existing technology to accommodate the images its scanners output, which could materially affect the ability of physicians to use the Heartflow Platform, increase our R&D expenses, and could adversely affect our business, financial condition, results of operations and prospects.

The size and expected growth of our addressable market may be smaller than we estimate.

Our estimate of the addressable market for our current products and any future products is subject to significant uncertainty and is based on assumptions and estimates, including our internal analysis and industry experience. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. As a result, our estimates of the addressable market for our current or future products may prove to be incorrect. Moreover, our ability to serve a significant portion of this estimated market is subject to many factors, including our success in promoting the use of CCTA as a non-invasive diagnostic test that can be combined with the Heartflow Platform, which is subject to many risks and uncertainties, and relies on the availability and proximity of healthcare facilities with active CCTA programs to the patients in our estimated market. Accordingly, if we are unable to increase the use of CCTA at the rates we estimate, if the actual number of patients who would benefit from our products is less than we estimate, or if the price at which we can sell future products or the reimbursement rate received by healthcare providers is less than we estimate, the size and expected growth of our addressable market would be smaller than our estimates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in updating or otherwise enhancing the Heartflow Platform.

A part of our strategy is bringing new enhancements to our customers through updates to the Heartflow Platform, which may include offering new products, additional features, applications and improvements to our technology. We expect to make significant investments to advance these efforts, and enhancing the Heartflow Platform is a complex and time-consuming endeavor. New products, additional features, applications and improvements to our technology that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy, utility or user friendliness. Product development and improvement is expensive, may take months or years to complete and can have uncertain outcomes. Failure can occur at any stage of the development or improvement process and may occur only after substantial work has been completed, or after completion.

Even if, after development, an updated product appears successful, we may, depending on the nature of the update, need to obtain regulatory clearances, authorizations or approvals before we can market the updated product. Such regulatory clearances, authorizations or approvals are likely to require significant time and expenditures and the applicable regulatory authority may not clear, authorize or approve any

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product, update or new product we develop. Obtaining such clearances, authorizations or approvals may require data from clinical trials, which can be costly and time-consuming to obtain. In certain jurisdictions

or in certain cases, clinical data may also be required in order to obtain reimbursement coverage, and this clinical data may be in addition to data required to obtain regulatory clearances, authorizations or approvals. Some clinical studies may fail to meet their endpoints, introducing risk or delay in the ability to commercialize a new feature or product. In light of these requirements, we may choose to limit the scope of any new products, additional features, applications and improvements we seek to develop.

Even if we develop a product update or new product that receives regulatory clearance, authorization or approval, and for which we obtain sufficient commercial third party and government reimbursement coverage, we would need to commit substantial resources to commercialize and market the updated product, new product or new application of our existing product, which may never achieve market acceptance among various stakeholders or be commercially successful. Further, the applicable regulations or the application of those regulations could change in ways that would impact the Heartflow Platform and our ability to successfully manufacture or market our products. The expenses or losses associated with unsuccessful updates to or expansion of the Heartflow Platform could adversely affect our business, financial condition, results of operations and prospects.

The commercialization of Heartflow Plaque Analysis is nascent, and we may not be able to achieve or maintain sufficient market acceptance or the levels of utilization we expect from Heartflow Plaque Analysis or any other future product.

We began limited market education efforts for our Heartflow Plaque Analysis in the second half of 2023, and we have generated very minimal revenue from this product. HeartFlow Plaque Analysis is covered by all seven local Medicare Administrative Contractors (MACs) regions and select commercial payors. However, the coverage criteria, timing, commercial payor reimbursement rates and availability of coverage are still evolving and may vary by payor and jurisdiction, and other payors may not adopt similar coverage policies. As a result, even with these developments, we may not be able to achieve customer acceptance or broad commercial reimbursement coverage, which could limit its adoption.

The market for alternative plaque analysis products is competitive in terms of development, availability, pricing, product quality and time-to-market. We face competition from companies that provide or are developing similar plaque analysis products, which may distinguish themselves from us through, among other things, perceived product quality, style and visuals, sleek design, enhanced user-friendliness and innovative features. In addition, some of these competitors are agile, early-stage companies that may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements in the plaque analysis category. Some of these competitors commercially launched competing plaque analysis products prior to our launch of Heartflow Plaque Analysis and may have a first-mover advantage as a result. For more information on risks related to our competition, see the risk factor titled "We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may develop products that are more effective, accurate, reliable, cost-effective or more advanced than ours, which may harm our financial condition. If we are unable to compete successfully or our potential market share is reduced, we may be unable to increase or sustain our revenue or achieve profitability."

Our competitors may also be able to offer plaque analysis products similar or superior to ours at a more attractive price than we can or may be better positioned to serve certain segments of our market, which could create additional price pressure. For example, our competitors have in the past, and may in the future, offer plaque analysis and other products at a more attractive price than we can such that current or potential customers may select our competitors' products in lieu of purchasing and using our Heartflow Plaque Analysis. Moreover, our competitors have in the past, and may in the future, suggest that their plaque analysis and other products could replace both our Heartflow Plaque Analysis and our Heartflow FFR_{CT} Analysis, which would adversely affect our ability to achieve sufficient market acceptance for our Heartflow Plaque Analysis, could affect sales of our Heartflow FFR_{CT} Analysis and could cause our Heartflow FFR_{CT} Analysis to lose market share. While we believe Heartflow Plaque Analysis represents a

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significant long-term opportunity for us, there can be no assurances that we will successfully compete in such market and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We face risks associated with our use and development of AI models, which may result in operational challenges, legal liability, reputational concerns and competitive risks.

We use and develop AI and automated analysis and decision-making technologies, including proprietary AI algorithms and models and computational fluid dynamics (collectively, "AI Technologies") to power the Heartflow Platform. In addition, we use AI Technologies to drive improvements in the performance of the Heartflow Platform. We expect that significant increased investment will be required in the future to improve our use and development of AI Technologies.

As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies. In particular, if the AI Technologies underlying our Heartflow Platform are incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate or otherwise poor quality data; used without sufficient oversight and quality control; misused or used outside of scope of applicable regulatory authorizations; and/or adversely impacted by unforeseen bugs, defects, technical challenges, cybersecurity threats or material performance issues, the performance of our Heartflow Platform and business, as well as our reputation and the reputations of our customers, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party, regulatory enforcement actions or civil claims. This could result in fines, penalties and damage awards and disgorgement of any output, development or technology developed as a result of such violations.

In addition, we leverage a human-in-the-loop AI system that combines advanced algorithms with an analyst-based quality inspection and monitoring process to create patient-specific reports based on CCTA images. While we constantly work to improve our Heartflow Platform and algorithms, the AI Technologies we work with are novel and complex, and we cannot assure you that our AI Technologies will be able to perform as intended under all circumstances, or that our analyst-based review process will identify and correct any errors in the outputs of our AI Technologies.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state and foreign government bodies and agencies have introduced or are currently considering additional laws, regulations

and guidance. For example, the FDA has issued guidance documents relating to the incorporation of AI technologies into medical devices and marketing submissions for AI-enabled devices. Specifically, draft guidance issued on January 7, 2025, titled Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations, proposes recommendations for the design, development and implementation of AI-enabled devices that the FDA encourages manufacturers consider using throughout the total product lifecycle. In addition, the California Privacy Protection Agency has approved for rulemaking regulations under the CCPA regarding the use of automated decision-making that may require assessing risks and to provide notice and rights to opt-out and access to information underlying the logic and outputs. Colorado passed the Colorado AI Act, which will go into effect in February 2026. This law creates duties for developers and deployers to use reasonable care to protect consumers from any known or reasonably foreseeable risks of “algorithmic discrimination” arising from the intended and contracted uses of “high-risk AI systems,” including those that impact healthcare services. Such additional laws, regulations and guidance may impact our ability to develop, use and commercialize AI Technologies in the future.

It is possible that further new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our Heartflow Platform and the way in which we use AI Technologies. We may need to expend resources to adjust our Heartflow Platform in certain jurisdictions if the laws, regulations or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by

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imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations and prospects.

Our Heartflow Platform and the data and models it generates could have bugs, defects or errors, including human quality control errors, or otherwise fail to meet the expectations of patients, physicians and third-party payors, which could adversely affect our reputation, business and operating results.

We cannot provide assurance that the proprietary technology and algorithms used in our Heartflow Platform do not contain undetected bugs, defects or errors or that our analyst-based review process will identify and correct any errors in the outputs of our AI Technologies. We cannot provide assurance that the inbound CCTA images and image quality will always allow a true representation of the patient anatomy, and any such limitations in CCTA images could affect the results of our analyses. We have in the past, and may in the future, experience defects or errors in our Heartflow Platform or the data and models it generates that remain undetected by our analyst-based review process, and our reputation, business and operating results could be adversely affected.

Furthermore, the success of the Heartflow Platform depends in part on patients', physicians' and third-party payors' confidence that our platform can provide reliable, high-quality actionable data and analysis that will improve clinical decision making. We believe that patients, physicians and third-party payors are likely to be sensitive to product defects and errors in the use of our products, including if the defects and errors affect a physician's ability to use the CCTA imaging results or result in a misdiagnosis. In the past, we have experienced software code defects and software release process defects that have resulted in intermittent interruptions to the physician's ability to use our Heartflow Platform, and we may experience such defects in the future. A subset of these defects were reported as part of the FDA's Manufacturer and User Facility Device Experience (“MAUDE”) disclosure. For more information, see the risk factor titled “The Heartflow Platform may be subject to recalls, which could be costly and could harm our reputation and business.” As a result, the failure of our Heartflow Platform to perform as expected, including to reduce unnecessary invasive testing or fail to enable physicians to optimize treatment planning or provide more efficient care, could significantly impact a physician's willingness to use and rely on the Heartflow Platform, which would impair our operating results and our reputation. In addition, we may be subject to legal claims arising from any such failures.

Bugs, defects or errors in the Heartflow Platform or the failure of third-party service providers we rely on, such as Amazon Web Services (“AWS”) or other cloud storage and telecommunications services providers, to block a virus or prevent a security breach could harm our reputation and adversely impact our results of operations. Defects may cause our products to be vulnerable to security attacks, cause them to fail to produce accurate results or temporarily interrupt our commercial operations. Because the techniques used by computer hackers to access or sabotage networks change frequently and generally are not recognized until launched against a target, we or our third-party services providers may be unable to anticipate these techniques and provide a corrective measure in time to protect the Heartflow Platform and our networks. Potential defects may further cause the platform to be unavailable for a period of time, affect ability of a customer to access information, result in a slow or suboptimal user experience, impact turnaround time of an analysis, or provide other forms of degradation to the overall service.

We depend on our talent to grow and operate our business, and if we are unable to hire, integrate, develop, motivate and retain our personnel, including highly qualified, technical personnel, we may not be able to grow effectively and this could adversely affect our business.

To execute our growth plan, we must attract and retain highly qualified, technical personnel. Competition for these personnel is intense, especially for engineers with high levels of expertise in AI, cloud architecture, 3D visualization, research scientists and senior sales executives with experience in the cardiology industry. We may experience difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater

resources than we have. We also compete with companies that are believed to have high potential growth opportunities or that have experienced rapid recent growth.

Our future success depends in part on our ability to continue to retain our executive officers and other key employees and to recruit and hire new employees, including engineers, research scientists, case analysts and production team members. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our development, research and commercialization objectives. Any of our executive officers and other employees may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines or is perceived to be less valuable than stock awards of other competing employers, it may adversely affect our ability to recruit and retain highly skilled employees. In addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. If we fail to attract new personnel, or fail to retain and motivate our current personnel, our business and prospects could be adversely affected.

If we fail to properly manage our future growth, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. Our future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In order to manage our operations and growth we will need to continue to improve our operational and management controls, administrative and operational infrastructure, reporting and information technology systems and financial internal control procedures. Due to our limited financial resources and the limited experience of our management team in managing a company with such future growth expectations, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, as demand for the Heartflow Platform increases, we will need to scale our capacity, expand customer service and enhance our internal quality assurance program. We may fail to implement any increases in scale, related improvements and quality assurance, and we may fail to find appropriate personnel to facilitate the growth of our business. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and expansion of our operations. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of any new products. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our Heartflow Plaque Analysis or any of our future products will depend in part on our ability to effectively manage the future growth and expansion of our company. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business, financial condition, results of operations and prospects may be adversely affected.

Our business could be disrupted by catastrophic events.

The occurrence of any catastrophic event, including earthquake, fire, flood, tsunami or other weather event, power loss, telecommunications failure, software or hardware malfunctions, pandemics, political unrest, geopolitical instability, severe or prolonged economic downturn, including domestic and global inflationary trends, interest rate volatility, and uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, cyberattack (including a ransomware attack), war or terrorist attack, could result in lengthy interruptions in our ability to serve our customers. In addition, acts of terrorism could cause disruptions to the internet or the economy as a whole and could disproportionately affect us given our reliance on the internet and cloud-based services. Specifically, our corporate headquarters are located in Mountain View, California and our production-related computers are currently located in our Mountain View office and in Austin, Texas. California is considered to be an active earthquake zone, is prone to catastrophic fires, severe weather events and the follow-on effects thereof, including tsunamis, mudslides, flooding, power outages and other events that could disrupt our business. Texas is also subject to severe weather events, power outages and other events that could disrupt our business. Any event that prevents our access to such facilities, physically or virtually, would prevent us from operating our business and have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, we rely on our network and third-party infrastructure, including our cloud-based infrastructure which we outsource to AWS, enterprise applications, internal technology systems and our website, for our development, marketing, operational support-hosted services and sales activities. In the event of a catastrophic event, we may be unable to continue our operations and may endure system interruptions, delays in our ability to generate reports and output them to physicians, reputational harm, delays in our product development, breaches of data security and loss of critical data, all of which could have an

adverse effect on our future operating results. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster and to execute successfully on those plans in the event of a disaster or emergency, our business would be harmed. Even with our disaster recovery arrangements and insurance coverage, the ability of our customers to access and utilize our Heartflow Platform could be interrupted, or we could lose critical data, which would have a negative impact on our business.

In addition, the occurrence of a catastrophic event could impact providers of CCTAs, contrast agents for CCTAs or suppliers of iodinated contrast media or similar supplies that are necessary to perform CCTAs. For example, in 2022, the shutdown of an iodinated contrast media manufacturing facility led to a significant shortage of iodinated contrast media, which resulted in the cancellation or rescheduling of non-urgent contrast-requiring cardiac procedures and imaging. Any of these events could affect demand for the Heartflow Platform, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Consolidation among healthcare providers could have an adverse effect on our business, financial condition, results of operations and prospects.

In the United States, there has been a trend of consolidation among healthcare providers and purchasers of medical technology devices, often to gain greater market power. As healthcare providers consolidate, they may try to use their market power to negotiate price concessions or reductions for the products and services they purchase and use, including our Heartflow Platform. As a result, it is unknown whether such purchasers will decide to stop purchasing our Heartflow Platform or demand discounts on our prices. If we reduce our prices in response to these industry trends, our revenue would decrease, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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We may acquire other companies, solutions or technologies, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in companies, solutions or technologies that we believe could complement or expand our products, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions or other investment opportunities may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable transactions, whether or not they are consummated.

If we acquire any businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including: inability to integrate or benefit from acquired technologies or services in a profitable manner; unanticipated costs or liabilities associated with the acquisition; incurrence of acquisition-related costs; difficulty integrating the accounting systems, operations and personnel of the acquired business; difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business; diversion of management's attention from other business concerns; use of resources that are needed in other parts of our business; adverse effects on our existing business relationships with business partners and customers as a result of the acquisition; the potential loss of key employees; and use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of any companies, solutions or technologies that we may acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results and cause the market price of our common stock to decline. If an acquired company, solution or technology fails to meet our expectations and does not complement or expand our products, enhance our technical capabilities or otherwise offer growth opportunities, our business, financial condition, results of operations and prospects may suffer.

Sales to customers outside the United States or with international operations expose us to risks inherent in international sales.

In the three months ended September 30, 2025 and 2024, sales to customers outside the United States accounted for approximately 7% and 8%, respectively, and accounted for approximately 8% and 9% of our revenue in the nine months ended September 30, 2025 and 2024, respectively. One element of our growth strategy is to further expand our international operations and worldwide customer base. Operating in international markets requires significant resources and management attention and subjects us to regulatory, economic and political risks that are different from those in the United States.

We have limited operating experience in international markets, and we cannot assure you that our existing presence in the United Kingdom, Europe and Japan or any expansion efforts into other international markets will be successful. Our experience in the United States and international markets may not be relevant to our ability to expand in other markets. Our international expansion efforts may not be successful in creating further demand for our products outside of the United States or in effectively selling our products in the international markets we enter. In addition, expansion into other international markets will be costly and will impose additional burdens on our executive and administrative personnel, finance and legal teams, sales and marketing teams and general managerial resources. If our efforts to introduce our products into other international markets are not successful, we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for international expansion could exceed the results of operations generated from this expansion.

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In addition, we operate in an industry which is subject to significant enforcement scrutiny by both U.S. and non-U.S. government authorities. Our international business requires us to comply with U.S. and foreign laws and regulations, such as various anti-bribery and anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.S. Fraud Act and in certain cases the U.K. Bribery Act of 2010. Compliance with these is costly and exposes us to significant civil and criminal penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative fines, penalties and disgorgement of profits, including imprisonment of individuals, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Our international operations expose us to risks inherent in operating in foreign jurisdictions that could adversely affect our business.

If we do not obtain and maintain international regulatory registrations, clearances or approvals for our Heartflow Platform, we will be unable to market and sell our products outside of the United States.

Any future sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance or approval of a specified regulatory authority or a Certificate of Conformity of a notified body. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time consuming and we may not receive regulatory clearances or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for regulatory clearances or approvals before we are permitted to sell the modified product.

In addition, All governing regulations around medical devices evolve rapidly, and we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory registration, clearance, marketing authorization, or approval by the FDA does not ensure registration, clearance, marketing authorization, or approval by foreign regulatory authorities or authorized representatives in other countries. Registration, clearance, marketing authorization, or approval by one or more foreign regulatory authorities or authorized representatives do not ensure registration, clearance, marketing authorization, or approval by regulatory authorities in other foreign countries or by the FDA. Nevertheless, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Risks Related to Data Privacy and Information Technology

Failure to comply with laws and regulations affecting the transmission, security and privacy of personal information (including health information) could result in significant penalties.

Federal, state and foreign government bodies and authorities have adopted, are considering adopting, or may adopt laws and regulations regarding the collection, use, processing, storage and disclosure of personal information obtained from consumers and individuals. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). Under these laws we may be required to obtain certain consents to process personal data. For example, some of our data processing practices have been, and may in the future continue to be, subject to challenges or lawsuits under privacy, security, and communications laws, including, for example, challenges based on wiretapping laws

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for sharing consumer information with third parties through various methods, such as via third-party marketing pixels or software development kits. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands. In addition, numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), govern the collection, dissemination, security, use and confidentiality of patient identifiable health information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of health information within our company and with third parties. The Standards for Privacy of Individually Identifiable Health Information ("Privacy Standards"), and the Security Standards for the Protection of Electronic Protected Health Information ("Security Standards"), under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. As a result, both covered entities and business associates can be subject to significant civil and criminal penalties for failure to comply with the Privacy Standards or the Security Standards.

HIPAA, the HITECH Act and the Affordable Care Act ("ACA") also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, unique identifiers, operating rules. Companies that bill payors for healthcare-related services and device use are required to conform to the transaction standards. CMS, on behalf of HHS, has the authority to investigate complaints and audit for compliance with the HIPAA standards for transactions, code sets, unique identifiers and operating rules, including the Administrative Simplification provisions of HIPAA and the ACA. Failure to comply with these standards, and any investigation or audit and penalties imposed may have an adverse impact on our business. HIPAA requires covered entities and business associates to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of patient identifiable health information, restricts certain disclosures and sales of patient identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The Final HIPAA Omnibus Rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, states have adopted comparable privacy and security laws and regulations that differ somewhat from federal and other states' laws, and that govern where more stringent than federal law.

As a business associate under HIPAA, if we do not comply with the requirements of HIPAA, the HITECH Act or applicable state privacy and security laws, we could be subject to criminal or civil sanctions that could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are substantial and could have an adverse effect on our business. In addition, we are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. In addition, a security breach could require reporting to federal and state government entities, notification to affected individuals, expensive investigation and remediation and mitigation. Government agencies could, in their discretion, impose fines and penalties relating to the breach, that would have an adverse effect on our business.

Foreign data privacy regulations, such as the General Data Protection Regulation (E.U.) 2016/679, the European Union's Data Protection Directive ("Directive 95/46/EC"), and the country specific regulations that implement Directive 95/46/EC, also govern the processing of personally identifiable data, and a number of these regulations are stricter than U.S. laws.

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In addition, many states have laws, regulations and other authorities that govern data privacy, security and breach notification. While some of these laws exempt protected health information subject to HIPAA, they may apply to other personal information we collect, including personal information collected from employees or from visitors to our website. Failure to comply with these authorities may have an adverse impact on our business.

We expect to expend significant resources to comply with these laws and regulations. The functional and operational requirements and costs of compliance with such laws and regulations may adversely impact our business, and failure to enable our solutions to comply with such laws and regulations could lead to significant fines and penalties imposed by regulators, as well as claims, lawsuits and contractual indemnification obligations by or for our customers or third parties and significant reputational harm.

We depend on our information technology systems, and any failure of these systems could harm our business and adversely affect our business and operating results.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, failures during the processes of upgrading or replacing software, power outages, hardware failures, user or human errors and natural disasters. Moreover, despite network security and back up measures, some of our servers are potentially vulnerable to cybersecurity incidents, including phishing attacks by computer hackers or other malicious human acts, computer viruses, ransomware, malware and similar disruptive problems or other methods of compromising employee or customer administrator credentials to access protected health information and our internal data. Failures or significant downtime of our information technology or telecommunications systems could prevent us from operating our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our operating results may suffer.

In addition, our brand, reputation and ability to attract, retain and serve our customers are dependent upon the reliable performance of our Heartflow Platform, including our underlying information technology systems and infrastructure. Our technical infrastructure may not be adequately designed with sufficient reliability and redundancy to avoid performance delays or outages that could be harmful to our business. If our Heartflow Platform is unavailable when physicians attempt to access it, or if it does not load as quickly as they expect, physicians may not use our Heartflow Platform as often in the future, or at all. As our customer base continues to grow, we will need an increasing amount of technical infrastructure, including network capacity and computing power, to continue to satisfy the needs of our users.

We rely upon AWS to operate our cloud offering; any disruption of or interference with our use of AWS would adversely affect our business, results of operations and financial condition.

We outsource all of our cloud-based infrastructure to AWS. Our customers need to be able to access our cloud-based infrastructure at any time, without interruption or degradation of performance. AWS runs its own platform that we access, and we are, therefore, vulnerable to service interruptions at AWS. We may experience interruptions, delays and outages in service and availability from time to time as a result of problems with our AWS provided infrastructure. For example, in October 2025 and at other times in the past, AWS has suffered significant outages that had a widespread impact on cloud-based software and services companies. Although our cloud offering has not been affected by these outages, a similar outage could render our cloud offering inaccessible to customers, and such outages may be prolonged. Additionally, AWS has suffered outages at specific customer locations in the past, rendering the customer unable to access our offering for periods of time. Lack of availability of our AWS infrastructure could be

due to a number of potential causes including technical failures, natural disasters, fraud or security attacks that we cannot predict or prevent.

In addition, if the security of the AWS infrastructure is compromised or believed to have been compromised, our business, results of operations and financial condition could be adversely affected. It is possible that our customers and potential customers would hold us accountable for any breach of security affecting the AWS infrastructure and we may incur significant liability from those customers and from third

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parties with respect to any breach affecting AWS systems. For more information, see the risk factor titled "Failure to comply with laws and regulations affecting the transmission, security and privacy of personal information (including health information) could result in significant penalties." Because our agreement with AWS limits AWS' liability for damages, we may not be able to recover a material portion of our liabilities to our customers and third parties from AWS. Customers and potential customers may refuse to do business with us because of the perceived or actual failure of our cloud offering as hosted by AWS and our operating results could be harmed.

Our agreement with AWS allows AWS to terminate the agreement by providing 30 days' advance notice, and allows AWS to terminate in case of a material breach of contract if such breach is uncured for 30 days following receipt of notice of such breach, or to terminate immediately upon notice to us (i) if AWS has the right to suspend our account; (ii) if AWS' relationship with a third-party software or technology provider terminates, expires or requires AWS to change the way it provides its services; or (iii) in order to comply with the law or requests of governmental entities. Although we expect that we could receive similar services from other third parties, if any of our arrangements with AWS are terminated, we could experience interruptions on our platform and in our ability to make our platform available to customers, as well as delays and additional expenses in arranging alternative cloud infrastructure services.

If we fail to offer high quality customer support, our business and reputation could suffer.

Our customers rely on our customer support teams to resolve technical and operational issues if and when they arise. We may be unable to respond quickly enough to accommodate short-term increases in customer demand for customer support. We also may be unable to modify the nature, scope and delivery of our customer support to compete with changes in customer support services provided by our competitors or to adapt to product and industry developments. Increased customer demand for customer support, without corresponding revenue, could increase costs and harm our results of operations. In addition, as we continue to grow our operations and reach a large global customer base, we need to be able to provide efficient customer support that meets our customers' needs globally at scale. The number of our customers has grown significantly, and that growth has and will continue to put additional pressure on our support organization. As our business scales, we may need to engage third-party customer support service providers, which could negatively impact the quality of our customer support if such third parties are unable to provide customer support that is as effective as that we provide ourselves. Our sales are highly dependent on our business reputation and on positive recommendations from our existing customers. Accordingly, high quality customer support is important for the renewal and expansion of our agreements with existing customers and any failure to maintain such standards of customer support, or a market perception that we do not maintain high quality customer support, could harm our reputation, our ability to sell product to existing and prospective customers and our business, financial condition, results of operations and prospects.

We invest significantly in research and development, and to the extent our research and development investments do not translate into new products, features or improvements to our current products, or if we do not use those investments efficiently, our business, financial condition, results of operations and prospects would be harmed.

A key element of our strategy is to invest significantly in our research and development efforts to introduce new products, features and improvements aimed at increasing the value proposition of the Heartflow Platform for our customers. For the three months ended September 30, 2025 and 2024, our research and development expenses were 37% and 36% of our revenue, respectively, and 36% and 34% of our revenue for the nine months ended September 30, 2025 and 2024, respectively. If we do not spend our research and development budget efficiently or effectively on compelling innovation and technologies, our business may be harmed and we may not realize the expected benefits of our strategy. Moreover, research and development projects can be technically challenging and expensive. The nature of these research and development cycles may cause us to experience delays between the time we incur expenses associated with research and development and the time we are able to offer compelling solutions and generate revenue, if any, from such investment. For example, investments made to expand

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the Heartflow Platform to asymptomatic patients may be expensive, technically challenging, experience delays and may not be successful. Additionally, anticipated customer demand for a product or feature we are developing could decrease after the development cycle has commenced, and we would nonetheless be unable to avoid substantial costs associated with the development of any such product or features. If we expend a significant amount of resources on research and development and our efforts do not lead to the successful introduction or improvement of products or features that are competitive in our current or future markets, it would harm our business, financial condition, results of operations and prospects.

Our networks and those of our third-party service providers may become the target of bad actors or security breaches that we cannot anticipate or successfully defend, which could have an

adverse impact on our business.

The Heartflow Platform involves the storage and transmission of our customers' personal information or identifying information of their patients. Increasingly, we and other companies are subject to a wide variety of attacks on their networks on an ongoing basis. In addition to attacks from traditional computer "hackers," malicious code (such as viruses and worms), employee theft or misuse, ransomware attacks and denial of service attacks, sophisticated nation state and nation state supported actors now engage in intrusions and attacks (including advanced persistent threat intrusions), and add to the risks to our internal networks and the information they store and process. Additionally, such bad actors frequently attempt to fraudulently induce employees or customers into disclosing sensitive information such as user names, passwords or other information in order to gain access to our customers' data, their patient's data or our data, including our intellectual property and other confidential business information, or our information technology systems. Because techniques used to obtain unauthorized access or to sabotage systems change frequently and generally are not recognized until successfully launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures.

Despite significant efforts to create process and security barriers to such threats, it is virtually impossible for us to entirely mitigate these risks. Any such breach could compromise our networks, creating system disruptions or slowdowns and exploiting security vulnerabilities of our products, and the information stored on our networks could be accessed, publicly disclosed, lost or stolen, which could subject us to liability and cause us significant financial harm. Such breaches often result in reputational damage, negative publicity, loss of industry data security certifications, customers and sales, increased costs to remedy any problem, costly litigation and contractual indemnification obligations by or for impacted customers or third parties any of which could adversely affect our business. In addition, although we have, and intend to maintain, insurance with respect to any such indemnification obligations, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have an adverse effect on our business, financial condition, results of operations and prospects.

We also rely on third-party service providers, such as cloud storage and telecommunications services providers. Such service providers are also potentially vulnerable to cybersecurity incidents that could result in the interruption of their services to us or unauthorized access, use or disclosure of our confidential information and confidential information of our customers and protected health information of their patients.

Our products are also targets for malicious cybersecurity acts. While some of our products contain encryption or security algorithms to protect third-party content or patient information or other data stored in our products, these products could still be hacked or targeted by malicious software programs or other attacks or the encryption schemes could be compromised, breached or circumvented by motivated or sophisticated hackers, which could harm our business and our reputation. In addition, see the risk factor titled "Our Heartflow Platform and the data and models it generates could have bugs, defects or errors, including human quality control errors, or otherwise fail to meet the expectations of patients, physicians and third-party payors, which could adversely affect our reputation, business and operating results" for more information on bugs, defects or errors in the Heartflow Platform.

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Risks Related to Legal and Regulatory Matters

We face extensive regulatory requirements to bring our products to market, and our failure to receive and maintain regulatory clearances or approvals of our current and future products in the United States or abroad or to comply with medical device regulatory requirements could adversely affect our business.

In order to market any product, we must establish and comply with numerous and varying regulatory requirements that differ by country and by region within certain countries. Approval, clearance or marketing authorization in the United States by the FDA or by a regulatory authority or other body in another country does not ensure approval by the regulatory authorities in other countries or jurisdictions or ensure approval, clearance or other marketing authorization for the same conditions of use. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. In general, unless an exemption applies, in the United States, current and future versions of our products must receive pre-market notification ("510(k)"), de novo classification ("de novo") or pre-market approval ("PMA") from the FDA before they can be marketed in the United States. We cannot provide assurance that any of our future products, to the extent required, will be cleared, approved or otherwise authorized by the FDA through any of its pre-market review processes, or that the FDA will provide export certificates that are necessary to export certain products to certain countries. In addition, the national health or social security organizations of certain foreign countries, including those outside Europe, require our products to be qualified before they can be marketed in those countries. Failure to receive, or delays in the receipt of, relevant foreign qualifications in the European Economic Area or other foreign countries could have an adverse effect on our business.

Pre-market notification, de novo classification request or PMA applications may require support by data from clinical trials. We are subject to requirements to publicly register and report the results of our clinical trials. We must also abide by good clinical practice ("GCP") requirements in the conduct and documentation of our clinical trials and report to the FDA significant financial interests of investigators in any clinical trials we submit to support marketing applications for our products. We, the FDA or an institutional review board ("IRB"), may suspend or terminate clinical trials at any time on various grounds, including a finding that patients are being exposed to an unacceptable health risk or that the treatment does not have any effect. If the FDA considers data from our clinical trials to be actually or potentially biased due to investigators' financial interests, or unreliable due to GCP noncompliance, it can require us to implement extensive data analyses or other corrective actions, or exclude data from consideration in support of our marketing applications. These outcomes could result in delay or denial of FDA clearance or approval and could result in the need to conduct additional, costly and time-consuming clinical trials.

Additionally, we are required to obtain pre-market clearance or approval to market significantly modified versions of our currently cleared Heartflow Platform, as well as to market the existing product for new indications. The FDA requires us to make and document a determination as to whether or not a

modification requires a new 510(k) clearance, de novo classification or PMA approval; however, the FDA can review and disagree with our decision. Although we have received 510(k) clearance from the FDA for the current version of the Heartflow Platform, we may not be successful in receiving clearances, de novo classifications or approvals in the future or the FDA may not agree with our decisions not to seek clearances, de novo classifications or approvals for any new products or particular product modifications or updates. The FDA may require us to obtain a new 510(k) clearance, de novo classifications or approval for any past or future modification or a new indication for our existing products. Such submissions may require the development and submission of additional data, may be time consuming and costly, and ultimately may not be cleared or approved by the FDA.

If the FDA requires us to obtain pre-market clearances, de novo classifications or approvals for any marketed modification to a previously cleared version of the Heartflow Platform, we may be required to cease manufacturing and marketing of the modified product or to recall the modified product until we obtain such FDA marketing authorization. The FDA may not clear, grant or approve such submissions in a timely manner, if at all. The FDA also may change its policies, adopt additional regulations, or revise

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existing regulations, each of which could prevent or delay pre-market clearance, de novo classification or approval of our devices, or could impact our ability to market a device that was previously cleared. Any of the foregoing could adversely impact our business and financial condition.

In addition, the FDA and other comparable foreign regulatory authorities may delay, limit or deny clearance, de novo classification or approval of future versions of or future indications for our products or any other potential product for many reasons, including, among others:

- the results of our clinical trials may not meet the level of statistically significant and clinically meaningful efficacy with an acceptable safety profile as required by FDA, or other comparable regulatory authorities in other countries, for marketing approval;
- the FDA or other comparable regulatory authorities in other countries may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other comparable regulatory authorities in other countries may disagree with our interpretation of data from our clinical trials;
- the FDA or other comparable regulatory authorities in other countries may not accept data generated at one or more of our clinical trial sites;
- if our 510(k) notifications, de novo classification requests, PMA applications, or similar notifications or applications, if and when submitted, are reviewed by the FDA or other comparable regulatory authorities, as applicable, the regulatory authorities may have difficulties scheduling the necessary review meetings in a timely manner, or may recommend against clearance or approval of our application; or
- the FDA may determine that our 510(k) notifications for new indications, if and when submitted, must follow a different regulatory pathway than we have attempted, and there may be potentially extended standards, timelines, reviews (such as by an FDA Advisory Committee) and costs in order to pursue approval.

Further, the ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with manufacturers, and other related processes can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel, and statutory, regulatory and policy changes. Government shutdowns, if prolonged, can significantly impact the ability of government agencies upon which we rely, such as the FDA, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory clearance, de novo classification or approval for current or future versions of the Heartflow Platform and could result in difficulties and costs for us. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required marketing authorizations, or if marketing authorizations in international markets are delayed, our ability to realize the full market potential of our new potential products will be limited.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system could have an adverse effect on our business, financial condition, results of operations and prospects.

In the United States, there have been and continue to be a number of legislative and regulatory initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the U.S. healthcare system, some of which are intended to contain or reduce the costs of medical products and services, including our own products. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work

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requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace

exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. These changes may decrease patient access to advanced cardiovascular diagnostics, including Heartflow's FFRCT and Plaque Analysis products, particularly among lower-income and high-risk populations. In addition, reduced federal and state funding, caps on supplemental payments, and limits on provider revenue sources may constrain hospital and health system budgets, potentially slowing adoption of innovative diagnostics despite demonstrated clinical value.

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the diagnostic tests associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, particularly in light of the recent administration changes in the White House and Congress, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or whether any future legislation or regulation in the United States may negatively affect our business, financial condition, results of operations and prospects. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve or maintain profitability and the availability of capital.

Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which may prevent us from being able to generate additional revenue or attain profitability.

We are subject to many laws and governmental regulations affecting our marketed products, both domestically and internationally, and any adverse regulatory action may adversely affect our business, financial condition, results of operations and prospects.

The Heartflow Platform is subject to regulation by numerous government authorities, including the FDA and comparable foreign authorities, after clearance or approval of current and future versions of the product. To varying degrees, each of these authorities requires us to comply with laws and regulations governing the development, design, testing, manufacture, labeling, advertising, promotion, distribution, import and export of our products. The Heartflow Platform (also referred to as Heartflow Analysis, which consists of four main functions, the Heartflow FFR_{CT} Analysis, the Heartflow Plaque Analysis, the Heartflow RoadMap Analysis and the Heartflow PCI Planner (which we expect to launch in 2026)) has been cleared by the FDA (K213857), and only the Heartflow FFR_{CT} Analysis function of the Heartflow Platform is Conformité Européene Marked ("CE Marked") in the European Economic Area, the United Kingdom and Australia, received medical device licensing in Canada and has been approved for marketing authorization in Japan by the Pharmaceuticals and Medical Devices Agency ("PMDA"), all for specific indications for use. The Heartflow Platform has also been cleared by the equivalent regulatory authorities in Israel, Saudi Arabia and United Arab Emirates and licensed in Bahrain.

We 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, including requirements related to product and facility registration, device listing, adverse event reporting, reporting of recalls and field corrective actions, manufacturing, advertising, promotion, distribution, import, and export. In certain jurisdictions outside of the United States, we contract with third parties (i.e., notified bodies, authorized representatives, and manufacturing

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authorization holders) who either oversee regulatory compliance or assume regulatory responsibilities for our products distributed by those third parties. We are subject to periodic inspections and audits by the FDA, notified bodies, authorized representatives and comparable foreign authorities to determine compliance with regulatory requirements, including good manufacturing practices such as the Quality System Regulation of the FDA, Medical Device Single Audit Program, ISO 13485:2016, and EN ISO 13485:2021 concerning the EU, establishment registration and device listing, medical device reporting, vigilance reporting of adverse events, notification of corrections, recalls, field safety corrective actions and product labeling and marketing. These inspections and audits can result in inspectional observations or reports, warning letters or other forms of enforcement action. If the FDA or comparable foreign authorities conclude, as a result of these inspections or audits or from any other source of information, that we are not in compliance with applicable laws or regulations, or that our products are ineffective or pose an unreasonable health risk, such authorities could ban these products, suspend or cancel our marketing authorizations, impose "stop sale" and "stop import" orders, refuse to issue export certificates, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, require us to conduct post-market surveillance studies or change the labeling for our products, or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. Failure to comply with regulatory requirements may also subject us to additional administrative and judicially imposed sanctions, warning letters, civil and criminal penalties, injunctions, interruption of manufacturing or clinical trials, total or partial suspension of production and resulting adverse publicity.

Discovery of previously unknown problems with our products' design or manufacture may result in restrictions on the use of the Heartflow Platform, restrictions placed on us or our suppliers or withdrawal of the existing regulatory clearance of the Heartflow Platform. The FDA or comparable foreign authorities may also impose operating restrictions, enjoin and restrain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us or recommend criminal prosecution of our company. Adverse regulatory action of a certain magnitude may restrict us from effectively marketing and selling our products. In addition, negative publicity or product liability claims resulting from any adverse regulatory action could have an adverse effect on our business, financial condition, results of operations and prospects.

In many of the foreign countries in which we market our products, we are subject to extensive medical device regulations that are similar to those of the FDA, including those in Europe. The regulation of our

products in Europe falls within the European Economic Area, which consists of the 27 member states of the European Union, as well as Iceland, Liechtenstein and Norway. Only medical devices that comply with certain conformity requirements of the Medical Devices Regulation (E.U.) 2017/745 concerning Medical Devices, or the E.U. Medical Devices Directive, Directive 2006/114/EC are allowed to be marketed within the European Economic Area.

Foreign governmental regulations have become increasingly stringent and more extensive, and we may become subject to even more rigorous regulation by foreign governmental authorities in the future. Penalties for a company's noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and civil or criminal sanctions. In some jurisdictions, such as Germany, any violation of a law related to medical devices is also considered to be a violation of unfair competition law. In such cases, governmental authorities, our competitors and business or consumer associations may then file lawsuits to prohibit us from commercializing the Heartflow Platform in such jurisdictions. Our competitors may also sue us for damages. Any domestic or foreign governmental law or regulation imposed in the future may have an adverse effect on our business, financial condition, results of operations and prospects.

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Delays in the commencement or completion of future or ongoing clinical testing could result in increased costs to us and delay our ability to market the Heartflow Platform for additional indications.

We recently completed enrolling patients for our DECIDE clinical trial to evaluate our Heartflow Plaque Analysis in a real-world setting. We do not know whether our DECIDE clinical trial will be completed on schedule, or at all. The commencement or completion of clinical trials can be disrupted for a variety of reasons, including difficulties in:

- recruiting and enrolling patients to participate in, and investigators to conduct, a clinical trial;
- reaching agreements on acceptable terms with prospective clinical research organizations and trial sites;
- obtaining approval of an investigational device exemption, application from the FDA or equivalent authorization from foreign regulatory authorities, if required; or
- obtaining IRB approval to conduct a clinical trial at a prospective site.

A clinical trial may also be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or in accordance with our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- safety or effectiveness issues; or
- lack of adequate funding to continue the clinical trial.

In addition, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to respond to such changes, which could impact the cost, timing or successful completion of a clinical trial. If we experience delays in the commencement or completion of our clinical trials, the commercial prospects for additional indications for our products will be harmed.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, including our DECIDE clinical trial, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial or additional data collected at a later time. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line or preliminary data we previously announced. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in our share price.

Further, others, including the FDA and other regulatory authorities or other bodies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh

the importance of data differently, which could impact the value of the particular trial, or the approvability or potential for commercialization of the particular medical device. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. The interim, top-line or preliminary data that we report may differ from final results, and regulatory authorities and other bodies may disagree with the conclusions reached, which may harm our ability to obtain marketing authorization for, and commercialize, our future products, which could harm our business, financial condition, results of operations and prospects.

We may face product liability claims that could result in costly litigation and significant liabilities. We may not be able to maintain adequate product liability insurance.

Development, marketing and clinical testing of our products may expose us to product liability and other tort claims. Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have an adverse effect on our business, financial condition, results of operations and prospects. For example, the U.S. Supreme Court declined to hear an appeal where the U.S. Court of Appeals for the Ninth Circuit ruled that the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act did not preempt state laws in a product liability case involving a medical device company. If other courts in the United States adopt similar rulings, we may be subject to increased litigation risk in connection with our products. Product liability claims could negatively affect our reputation, product sales, and our ability to obtain and maintain regulatory approval for our products.

In addition, although we have product liability and clinical study liability insurance, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost, on acceptable terms with adequate coverage, or at all, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have an adverse effect on our reputation, business, financial condition, results of operations and prospects.

The Heartflow Platform may be subject to recalls, which could be costly and could harm our reputation and business.

We are subject to ongoing medical device reporting regulations that require us to report to the FDA or similar governmental authorities in other countries if our products cause, or contribute to, death or serious injury, or if they malfunction and would be likely to cause, or contribute to, death or serious injury if the malfunction were to recur. We could voluntarily elect to, or the FDA and similar governmental authorities in other countries could require us to, perform a correction, field safety corrective action, removal or other recall of our products in the event of material deficiencies or defects in design, manufacturing or labeling that could cause harm. Our products have been in the past, and may in the future, be the subject of medical device reports of adverse events with the MAUDE database, including reports of false negative results and incorrect or imprecise results or readings. Between 2017 and October 31, 2025, 132 Heartflow Platform MAUDE reports were made, with 109 of those reports due to false negative results, 20 reports due to incorrect, inadequate or imprecise results or readings, and three reports due to an adverse event without an identified device or use problem. While none of these MAUDE reports resulted in a mandated or voluntary correction, field safety action, removal or a recall, a government mandated or voluntary correction, field safety corrective action, removal or other recall could occur as a result of manufacturing errors or design defects, including defects in labeling. Any correction, field safety corrective action, removal or other recall would divert managerial and financial resources and could lead to a substantial loss of physician and patient confidence in our products and, consequently, have an adverse effect on our growth prospects or operating results. A correction, field safety corrective action, removal or other recall could also result in substantial litigation, including product liability claims, with liabilities well in

excess of our insurance coverage limits. Any of these events could have an adverse effect on our reputation, business, financial condition, results of operations and prospects.

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

The Heartflow Platform (also referred to as Heartflow Analysis, which consists of four main functions, the Heartflow FFR_{CT} Analysis, the Heartflow Plaque Analysis, the Heartflow RoadMap Analysis and the Heartflow PCI Planner (which we expect to launch in 2026)) has been cleared by the FDA (K213857), and only the Heartflow FFR_{CT} Analysis function of the Heartflow Platform is CE Marked in the European Economic Area, the United Kingdom and Australia, received medical device licensing in Canada and has been approved for marketing authorization in Japan by the PMDA, all for specific indications for use. The Heartflow Platform has also been cleared by the equivalent regulatory authorities in Israel, Saudi Arabia and United Arab Emirates and licensed in Bahrain. We may only promote or market our products for their specifically cleared or approved indications. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use ("off-label use").

If the FDA determines that our promotional materials or training constitute promotion of an off-label use, or if there are claims that are not adequately substantiated or that are otherwise false or misleading, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities, including the Federal Trade Commission or Department of Justice, might take action if they consider our business activities to constitute promotion of an off-label use or other unlawful promotion, which could result in significant penalties, including criminal, civil and administrative penalties, damages, fines,

discontent, exclusion from participation in government healthcare programs and the curtailment of our operations. Any of these events could significantly harm our business, results of operations, financial condition and prospects.

Further, the advertising and promotion of our products are subject to European Economic Area Member States laws implementing the Medical Devices Directive concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other European Economic Area Member State legislation governing the advertising and promotion of medical devices. European Economic Area Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary E.U. and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals harming our business, financial condition, results of operations and prospects.

We are subject to numerous federal, state and foreign healthcare fraud and abuse, compliance, transparency and privacy laws and regulations, and a failure to comply with such laws and regulations could have an adverse effect on our business; similarly, an investigation, inquiry or audit by a government agency that alleges violations of law or regulation may have an adverse effect on our business.

Our operations are, and will continue to be, directly and indirectly affected by various federal, state and/or foreign healthcare laws, including those described below. In particular, because the use of our products are directly or indirectly reimbursed by U.S. federal health care programs, for example Medicare, we are subject to the federal Anti-Kickback Statute, a criminal law that prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration in cash or in-kind (including any kickback or bribe, but also common forms of remuneration, such as service or consulting fees, service fees, meals, travel expenses, discounts or rebates), directly or indirectly, overtly or covertly, in cash or in-kind, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the referring, ordering, purchasing or leasing of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include

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anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of (or purchases, uses or recommendations of prescriptions, uses or purchases related to) federal healthcare program covered business, the Anti-Kickback Statute has been implicated and potentially violated. Our practices may not in all cases meet all of the criteria for safe harbor protection from Anti-Kickback Statute liability. Further, the ACA, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim for payment by a government health care program including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims laws.

The U.S. civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act also applies to false submissions that cause the government to not receive a benefit to which it is entitled, such as a discounted sales price for products covered by federal healthcare programs. Intent to deceive is not required to establish liability under the civil False Claims Act. In addition, the civil False Claims Act includes a whistleblower provision that allows private citizens to bring claims on behalf of the U.S. government alleging violations of the law. Whistleblowers may be entitled to up to as much as thirty percent (30%) of the government's financial recovery resulting from such claims. This incentivizes potential whistleblowers to file complaints in federal court, which complaints are relied upon heavily by the government to investigate and prosecute allegations of violations of both the civil False Claims Act and the Anti-Kickback Statute. U.S. enforcement authorities or private whistleblowers acting on behalf of the U.S. government may file complaints under the civil False Claims Act alleging that we have caused one or more of our customers to submit false submissions for reimbursement from federal health care programs, including Medicare, Medicaid, or the Veterans Affairs program due to alleged kickbacks, the sale of adulterated or misbranded products, or the provision of false or misleading information to our customers or other third parties. For example, in October 2025, we and certain of our employees received civil investigative demands (the "CID") from the U.S. Department of Justice, Civil Division, in connection with an investigation under the federal Anti-Kickback Statute and Civil False Claims Act (the "Investigation"). The CID requests information, documents, and testimony focused on our financial and contractual arrangements with providers and our sales and marketing activities. We are cooperating with the Investigation. We are unable to express a view at this time regarding the likely duration, or ultimate outcome, of the Investigation. Depending on the outcome of the Investigation, there may be a material impact on our business, results of operations, financial condition, or cash flows.

Additionally, under the federal Civil Money Penalty Statute, the Department of Health and Human Services ("HHS") may impose civil money penalties against entities that make offers to transfer or transfer remuneration, including gifts, payments or routine waivers of co-payments or deductibles, to any Medicare beneficiary in order to influence such individual to order or receive any item or service for which payment may be made, in whole or in part, under Medicare and/or a State health care program. The federal Civil Money Penalty Statute also creates potential civil liability, with a lower threshold for violation, of the same types of activities that would violate the criminal Anti-Kickback Statute.

Violations of these laws and regulations may result in significant criminal and/or civil fines and penalties, as well as potential exclusion from participation in federal health care programs, that could significantly impact our business and operations.

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We are also subject to other federal and state fraud and abuse laws, including HIPAA's fraud provisions, which among other things, are criminal laws that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully preventing, obstructing, misleading, delaying or attempting to delay a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. Many of these state laws closely mirror the federal Anti-Kickback Statute or civil False Claims Act but apply more broadly to products and services that are paid for in any way, whereas the federal law pertains only to those reimbursed by federal health care programs. In addition, many states have also adopted laws prohibiting fee-splitting (the sharing of professional fees with non-state licensed persons or entities), restricting marketing activities with physicians and/or prohibiting the practice of medicine (or the direction of the practice of medicine) by corporations or others that are not specifically licensed to practice medicine within the state. While under our model, licensed practitioners independently are providing any and all medical treatment and diagnostic services for which a state license is required, these state laws still may apply to us.

We also are subject to foreign fraud and abuse laws and regulations, which vary by country, and can prohibit many of the same activities addressed by U.S. laws.

We are also subject to the federal and state transparency reporting laws and regulations, gift bans and compliance reporting provisions. The Physician Payments Sunshine Act (also known as Open Payments) requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services information related to payments and other transfers of value provided directly or indirectly to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals. Such manufacturers are also required to annually report certain ownership and investment interests held by such U.S. physicians and their immediate family members. Certain states, like Massachusetts and Vermont, have similar reporting requirements. Some states, like Vermont, prohibit gifts and certain benefits from being provided to physicians licensed within that state. Other states, such as California and Nevada, mandate implementation of compliance programs to ensure compliance with fraud and abuse laws and regulations, as well as with industry codes of conduct, such as the AdvaMed Code of Ethics on Interactions with Health Care Professionals. Our business is subject to these many requirements, which can be nuanced and lacking in clear guidance. Our failure to comply with these laws or regulations could result in substantial fines or penalties. Further, our reports made pursuant to these laws may be used by enforcement authorities or whistleblowers to raise or substantiate allegations against us.

We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity that submits claims for payment to the Medicare or Medicaid programs, from referring Medicare or Medicaid patients for certain "designated health services," which include diagnostic imaging services related to our products, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. Many states have their own self-referral laws as well, which in some cases apply to all payors, not just Medicare and Medicaid.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to significant penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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We also note that there is risk of our being found in violation of these laws by the fact that many of them have not been fully, clearly or consistently interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, to achieve compliance with applicable federal and state privacy, security and electronic transaction laws, we may be required to modify our operations with respect to the handling of patient information. Similarly, to achieve compliance with other applicable federal and state anti-fraud, open payments or other healthcare regulations, we may be required to modify our operations. Implementing any of these modifications may prove costly. At this time, we are not able to determine the full consequences to us, including the total cost of compliance, of these various federal and state laws.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the U.K. Bribery Act of 2010 and Proceeds of Crime Act 2002 and

possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We use third-party representatives to support sales of our products abroad. In addition, as we increase our international sales and business, we may engage with additional business partners and third-party intermediaries to sell our products abroad and to obtain necessary permits, licenses and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens. As a general matter, enforcement actions and sanctions could harm our business, financial condition, results of operations and prospects.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our products are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Exports of our products must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including: the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. Obtaining the necessary authorizations, including any required license, for a

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particular sale may be time consuming, is not guaranteed and may result in the delay or loss of sales opportunities. In addition, changes in our products or changes in applicable export or import regulations may create delays in the introduction and sale of our products in international markets, prevent our customers with international operations from deploying our products or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import regulations, shift in the enforcement or scope of existing regulations or change in the countries, governments, persons or technologies targeted by such regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Furthermore, we incorporate encryption technology into certain of our products. Various countries regulate the import of certain encryption technology, including through import permitting and licensing requirements, and have enacted laws that could limit our ability to distribute our products or could limit our customers' ability to implement our products in those countries. Encrypted products and the underlying technology may also be subject to export control restrictions. Governmental regulation of encryption technology and regulation of imports or exports of encryption products, or our failure to obtain required import or export approval for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products, including with respect to new releases of our products, may create delays in the introduction of our products in international markets, prevent our customers with international operations from deploying our products throughout their globally distributed systems or, in some cases, prevent the export of our products to some countries altogether.

Moreover, U.S. export control laws and economic sanctions programs prohibit the shipment of certain products and services to countries, governments and persons that are subject to U.S. economic embargoes and trade sanctions. Any violations of such economic embargoes and trade sanction regulations could have negative consequences, including government investigations, penalties and reputational harm.

Any future litigation against us could be costly and time-consuming to defend.

We have been in the past, and we may become in the future, subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by our third-party vendors, our customers or their patients in connection with contractual disputes or the use of our Heartflow Platform, claims brought by us or by competitors related to intellectual property or employment claims made by our current or former employees. Litigation might result in substantial costs and may divert management's attention and resources, which might seriously harm our business, financial condition, results of operations and prospects. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available at all or on terms acceptable to us (including premium increases or the imposition of large deductible or co-insurance requirements). A claim brought against us that is uninsured or underinsured could result in unanticipated costs, potentially harming our business, financial condition, results of operations and prospects. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or at all or that our insurers will not deny coverage as to any future claim.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property rights, or the scope of our

rights is not sufficiently broad, third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our commercial success will depend, in part, on our ability to continue obtaining and maintaining intellectual property protection for our technology and products, in both the United States and certain other countries, successfully defending this intellectual property against third-party challenges and

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successfully enforcing this intellectual property to prevent third-party infringement. We rely upon a combination of patents, trade secrets, know-how, copyrights, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products.

Our ability to protect our technologies and products from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents in both the United States and certain other countries. The patent positions of medical technology and software companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions.

We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us, or if issued, the breadth of such patent coverage. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. It is also possible that we may fail to identify patentable aspects of inventions made in the course of our development and commercial activities before it is too late to obtain patent protection on such inventions. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned or licensed patents may be challenged in the courts or the patent offices of the United States or abroad. Such challenges may result in a loss of exclusivity or in the patent's claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop third parties from using or commercializing similar or identical products, or limit the duration of patent protection for our technology and products. In addition, changes in either the patent laws, implementing regulations or interpretations of patent laws in the United States or foreign countries may diminish the value of our patent rights.

Even if unchallenged, our owned or licensed patents may not provide us with exclusivity or commercial value for our products, or any significant protection against competitive products, or prevent others from designing around our claims. Our competitors might conduct research and development activities in countries where we do not have patent rights (or in those countries where we do, under safe harbor provisions) and then use the information learned from such activities to develop competitive products for sale in our major commercial markets. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our products under patent protection could be reduced. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Patent applications are generally maintained in confidence until publication. In the United States, for example, patent applications are maintained in secrecy for up to 18 months after their filing. Nonpublication requests may allow a United States patent application to go unpublished until issuance. Similarly, publication of discoveries in scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on our products. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge the validity of our patents or prevent a patent from issuing from a pending patent application.

In addition to patents, proprietary trade secrets and unpatented know-how are important to our business. For information about risks related to these intellectual property rights, see the risk factor titled "If we are unable to protect the disclosure and use of our confidential information and trade secrets, the value of our products and technologies and our business and competitive position could be harmed" below. We also rely on the trademarks we own to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us will be approved. Third parties may also

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oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Competitors or other parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid

or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

For information about risks related to our inability to protect our intellectual property rights outside the United States, see the risk factor titled “We may not be able to adequately protect our intellectual property rights throughout the world” below.

If we are unable to protect the disclosure and use of our confidential information and trade secrets, the value of our products and technologies and our business and competitive position could be harmed.

In addition to patent protection, we also rely on other intellectual property rights, including trade secrets, know-how, and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. Although we have taken steps to protect our trade secrets and unpatented know-how, including by entering into confidentiality agreements with third parties, and proprietary information and invention agreements with our employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our security measures may be breached, and we may not have adequate remedies for any such breach.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that information to compete with us. Any exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition, results of operations and prospects. In particular, a failure to protect our proprietary rights may allow competitors to copy our products or technologies, which could adversely affect our pricing and market share. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products or technologies that we consider proprietary.

Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality, non-disclosure and non-use provisions, and outcomes of such litigation are unpredictable. Enforcing a claim that a party illegally disclosed, used or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. While we use commonly accepted security measures, trade secret claims are often based on a combination of federal and state law in the United States, and the criteria for protection of trade secrets can vary among

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different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. Even if we were to be successful in the enforcement of our claims, we may not be able to obtain adequate remedies.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed to others.

Any collaboration or other engagement with third parties for the development of our products may require us, at times, to share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary Heartflow Platform is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets, and we may need to share our trade secrets and

proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The U.S. Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. We have systems in place to

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remind us to pay these fees, and we employ outside firms to remind us to pay annuity fees due to patent agencies on our patents and pending patent applications. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the relevant market, which would have an adverse effect on our business. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents.

Changes in patent law, precedents and policies in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Changes in either the patent laws or interpretations of patent laws in the United States or other jurisdictions may diminish the value of our intellectual property. In the United States, in certain circumstances, court rulings may narrow the scope of patent protection and weaken the rights of patent owners. We cannot predict how decisions by the courts, the U.S. Congress, the USPTO or changes in the patent laws of other jurisdictions may impact the value of our patents. Changes in the laws, regulations, precedents and procedures governing patents could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, patent coverage in medical devices and technologies is a subject of evolution and differences between countries. This is especially true of the definition of patentable subject matter which affects both computer-related inventions and biological inventions. This evolution may cause current granted patents to be considered non-patent eligible or prevent us from protecting future inventions. U.S. Supreme Court and Federal Circuit Court decisions interpreting and/or limiting the scope of patentable subject matter under 35 U.S.C. § 101, in addition to examination guidelines from the USPTO, have made it more difficult for patentees to obtain and/or maintain patent claims in the United States that are directed to medical technologies involving computer-implemented applications. Several precedential decisions regarding patentable subject matter are of particular relevance to patents in the computer-implemented applications space. Our efforts to seek patent protection for our technologies and products may be impacted by the evolving case law and guidance or procedures issued by the USPTO or authorities in other jurisdictions based on such evolving case law.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which significantly impacts European patents, including those granted before the introduction of the new unitary patent system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the ability to opt out of the jurisdiction of the UPC and remain as national patents in the UPC countries. The UPC will provide our competitors with a new forum to centrally revoke European patents and allow for the possibility of a competitor to obtain pan-European injunctions, since patents that remain under the

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jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict

with certainly the long-term effects of any potential changes. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

In addition, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Under this system, a third party that files a patent application in the USPTO before us could be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications.

The Leahy-Smith Act also changed the way patent applications are prosecuted, including by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings to attack the validity of a patent. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence might not be sufficient to invalidate the claim if presented in a federal court action. Accordingly, third parties may use USPTO proceedings to invalidate our patent claims that would not have been invalidated if first challenged in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to adequately protect our intellectual property rights throughout the world.

Our patent portfolio includes patents and patent applications in countries outside of the United States, including Japan, Korea, China, Canada, Australia, Israel, India and countries in Europe. The requirements for patentability differ from country to country, the breadth of allowed patent claims can be inconsistent, the scope of coverage provided by these patents varies and the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. In addition, filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized sale of our products.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result,

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patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that, depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to methods of treatment.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We do not seek or have patent rights in certain foreign countries in which a market may exist. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our products in all of our expected significant foreign markets. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could put our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

~~**We may be involved in lawsuits to protect or enforce our patents or other intellectual property, or the patents or other intellectual property, which could be expensive, time consuming and unsuccessful.**~~

Competitors or other third parties may infringe, misappropriate or otherwise violate our owned or licensed patents, trade secrets or other intellectual property. To counter infringement or unauthorized use, we may be compelled to file infringement or misappropriation claims, which can be expensive and time consuming. We do not carry intellectual property insurance that would cover such claims. In certain circumstances it may not be practicable or cost effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. If we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that our patent(s) are invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection covering our products. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

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Our defense of litigation may fail and, even if successful, may result in substantial costs and distract our management and other employees. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. For example, the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings. We may not be able to prevent, alone or with our suppliers, misappropriation of intellectual property rights important to our business, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Third-party defendants may challenge any patent we own or in-license through adversarial proceedings in the issuing offices, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. If a third party asserts a substantial new question of patentability against any claim of a U.S. patent we own or license, the USPTO may grant a request for reexamination, which may result in a loss of scope of some claims or a loss of the entire patent. The adoption of the Leahy-Smith Act has established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post grant review, on the basis of lower legal standards than reexamination and additional grounds. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or loss of the entire patent. Participation in adversarial proceedings is very complex, expensive and may divert our management's attention from our core business and may result in unfavorable outcomes that could adversely affect our ability to prevent third parties from competing with us.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property rights or alleging that we have violated the intellectual property rights or other proprietary rights of third parties.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our products and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The medical device industry is characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe on their intellectual property rights. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our products. This includes litigation, or threatened litigation, with non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patent rights or other intellectual property, for example, based on conflicting obligations of consultants or others who are involved in developing our products. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we

may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We employ individuals who were previously employed at other medical technology companies. In addition, we use publications that are subject to copyright, as well as proprietary information and materials from third parties in our research. Some of the information and materials we use from third parties may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials or know-how of others in their work for us. In addition, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or other third parties. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

An unfavorable outcome for any such claim could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court

of competent jurisdiction would invalidate the claims of any such U.S. patent. Foreign courts will have similar burdens to overcome in order to successfully challenge a third-party claim of patent infringement.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or on our business, financial condition, results of operations and prospects.

The terms of our patents may not be sufficiently long to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, but can be shorter due to terminal disclaimers or similar term reductions in other jurisdictions. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our technologies or products are obtained, once the patent term has expired, we may be open to competition. In addition, although upon issuance in the United States, a patent's term can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of products, patents protecting such potential products might expire before or shortly after such products are commercialized. If we do not have sufficient patent life to protect our technologies and products, our business, financial condition, results of operations and prospects will be adversely affected.

If we do not obtain additional protection under the Hatch-Waxman Amendments or similar foreign legislation, our business may be materially affected.

Depending upon the timing, duration and specifics of FDA marketing approval for our future products, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during product development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries or areas, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration of the term of any such extension is less than we request, our competitors may obtain approval for competing products following our patent expiration, and our ability to generate revenues may be adversely affected.

Open-source software licenses often impose unanticipated or unclear restrictions on us or could expose us to litigation, and using open-source software has inherent risks, any of which could impair our ability to successfully commercialize the Heartflow Platform.

Our technology platform implements software modules licensed to us by third parties under “open source” licenses. The terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in ways that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot be certain that our

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processes for controlling our use of open-source software in connection with our products will be effective. From time to time, we may face claims from third parties asserting ownership of, or demanding release of, the open-source software or derivative works that we developed using such software (which could include our proprietary source code), or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our proprietary code, to discontinue the sale of our products if re-engineering could not be accomplished on a timely or cost effective basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition, results of operations and prospects.

The use of open-source software may entail greater risks than the use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement or the quality or ownership of the code. Many of these risks cannot be eliminated, and could, if not properly addressed, negatively affect our business. We cannot be sure that all open source software is submitted for approval prior to use in connection with our products.

In addition, some open-source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open-source software we use. If we combine our proprietary software with open-source software in a certain manner, we could, under certain open-source licenses, be required to release portions of the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of sales for us.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our potential products but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our potential products may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our new potential products in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

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- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Financing and Tax Matters

We may require additional capital to support business growth, and this capital might not be available on terms favorable to us, or at all, and may dilute ownership of our common stock for our stockholders, including purchasers of common stock.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and opportunities, including the need to develop new products, enhance our existing products, enhance our operating infrastructure, potentially expand internationally and potentially acquire complementary businesses and technologies. In order to achieve these objectives, we may make future commitments of capital resources. Accordingly, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our stockholders, including any purchasers of common stock, could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Further, if additional financing is needed, we may not be able to obtain additional financing on terms favorable to us or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and responding to business challenges and opportunities.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly revenue and results of operations may fluctuate from quarter to quarter due to, among others, the following reasons:

- the level of physicians' acceptance and adoption of our products, and changes in the rates at which physicians order our Heartflow FFR_{CT} Analysis or the percentage of CCTA scans for which our Heartflow FFR_{CT} Analysis is ordered;
- determinations, including the timing of determinations, by payors concerning coverage and reimbursement of our products;
- changes in coverage amounts or government and payors' reimbursement policies;
- the timing, expense and results of research and development activities, clinical trials and any additional regulatory approvals;
- changes in AHA or ACC guidelines, or guidelines in other countries, that lower support for our products or elevate alternative products as the preferred pathway for diagnosis and management of CAD;
- fluctuations in our expenses associated with expanding our commercial operations and operating as a public company;
- patients meeting their annual health insurance deductible later in the calendar year;
- the introduction of new products and technologies by our competitors;
- changes in our pricing policies or in the pricing policies of our competitors;

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- the productivity of our sales and marketing teams, and their ability to identify physicians who consistently refer appropriate patients for CCTAs in accordance with AHA and ACC guidelines;
- quality problems with our products or the Heartflow Platform; and
- the impact of catastrophic events such as a pandemic, cybersecurity events, global business, political and economic instability, including domestic and global inflationary trends, interest rate volatility, and uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto.

Because of these and other factors, it is likely that in some future period our operating results will not meet investor expectations or those of public market analysts. Any unanticipated change in revenue or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in our stock price.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

The vast majority of our revenue and the majority of our expense and capital purchasing activities through

the nine months ended September 30, 2025 were transacted in U.S. dollars. Approximately 7% and 8% of our revenue for the three months ended September 30, 2025 and 2024, respectively, and approximately 8% and 9% of our revenue for the nine months ended September 30, 2025 and 2024, respectively, was generated from customers outside the United States. However, because a portion of our operations consists of business activities outside of the United States, we have foreign currency operating expenses as well as asset and liability balances. During the nine months ended September 30, 2025, we were exposed to foreign currency risks in connection with our non-U.S. operations, and we anticipate that, over time, an increasing portion of our international agreements may provide for payment denominated in foreign currencies. Changes in the exchange rates between such foreign currencies and the U.S. dollar could therefore materially impact our reported results of operations and distort period-to-period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock could be adversely affected.

We do not currently engage in currency hedging activities to limit the risk of exchange rate fluctuations. In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations but we may not be successful in doing so. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations.

As of December 31, 2024, we had net operating loss ("NOL") carryforwards of approximately \$542.9 million and \$435.5 million for federal and state income tax purposes, respectively, which may be utilized against future federal and state income taxes. Federal NOL carryforwards we generated in tax years through December 31, 2017 generally may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017 generally may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually for tax years beginning after December 31, 2017.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards and other tax attributes, such as research and development tax credits, to offset future taxable income and taxes. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of our

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common stock, applying certain look through and aggregation rules, increases by more than 50% over such stockholders' lowest percentage ownership during the testing period, generally three years. Purchases of our common stock in amounts greater than specified levels, which will be beyond our control, could create a limitation on our ability to utilize our NOL carryforwards for tax purposes in the future. We completed a Section 382 study of our historic ownership changes through December 31, 2024 and no significant limitations were identified. In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOL carryforwards and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused.

If we are limited in our ability to use our NOL and tax credit carryforwards in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOL and tax credit carryforwards, and we could be required to pay taxes earlier than we would otherwise be required, which could cause such NOLs to expire unused. This could adversely affect our results of operations. Furthermore, we may not be able to generate sufficient taxable income to utilize our pre-2018 NOLs before they expire beginning in 2030. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs, and our business, financial condition, results of operations and prospects may be adversely affected as a result.

Our international operations subject us to potentially adverse tax consequences.

We currently report our taxable income in various jurisdictions based upon our business operations in those jurisdictions, including in the United States, United Kingdom, and Japan. We may in the future be subject to reporting requirements in other foreign jurisdictions. The international nature and organization of our business activities are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. We believe that our consolidated financial statements reflect adequate reserves to cover such a contingency, but there can be no assurances in that regard.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations or rates, both within and outside the United States, structural changes in our business, new accounting pronouncements or changes to existing accounting pronouncements, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenue and income before taxes in the various jurisdictions in which we operate that have different statutory tax rates, the future levels of tax benefits of equity-based compensation, changes in overall levels of pretax earnings or changes in the valuation of our deferred tax assets and liabilities. Additionally, we could be challenged by state and local tax authorities as to the propriety of our sales tax compliance, and our results could be materially impacted by these compliance determinations.

In addition, our effective tax rate may vary significantly depending on the market price of our common stock. The tax effects of the accounting for share-based compensation may significantly impact our

effective tax rate from period to period. In periods in which the market price of our common stock is higher than the grant price of the share-based compensation vesting in that period, we will recognize excess tax benefits that will decrease our effective tax rate. In future periods in which our stock price is lower than the grant price of the share-based compensation vesting in that period, our effective tax rate may increase. The amount and value of share-based compensation issued relative to our earnings in a particular period will also affect the magnitude of the impact of share-based compensation on our effective tax rate. These tax effects are dependent on the market price of our common stock, which we do not

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control, and a decline in our stock price could significantly increase our effective tax rate and adversely affect our financial condition.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and we could be subject to tax liabilities with respect to past or future sales, which could adversely affect our results of operations.

We do not collect sales and use, value added and similar taxes in all jurisdictions in which we have sales, based on our belief that such taxes are not applicable or that we are not required to collect such taxes with respect to the jurisdiction. Sales and use, value added and similar tax laws and rates vary greatly by jurisdiction. Certain jurisdictions in which we do not collect such taxes may assert that such taxes are applicable, which could result in tax assessments, penalties and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may adversely affect our results of operations.

Risks related to our common stock

There may not be a sustainable trading market for our common stock.

Prior to our IPO, there was no public market for our common stock. It is possible that an active trading market will not develop or, if developed, that any market will not be sustained, which would make it difficult for you to sell your shares of common stock at an attractive price or at all. An inactive market may also impair our ability to raise capital, to attract and motivate our employees through equity incentive awards and our ability to acquire businesses, brands, assets or technologies by using shares of our common stock as consideration.

The market price of our common stock may be volatile, which could cause the value of your investment to decline and could result in substantial losses for investors.

The market price of our common stock may be highly volatile and could be subject to wide fluctuations due to a variety of factors, some of which may be beyond our control, including:

- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- quarterly variations in our or our competitors results of operations;
- periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- future sales of our common stock or other securities, by us or our stockholders, as well as the expiration of lock-up agreements;
- the trading volume of our common stock;
- general economic, industry, market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including inflation, interest rate volatility, and uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto;
- changes in reimbursement by current or potential payors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- actual or anticipated changes in regulatory oversight of our products;

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- the results of our clinical trials;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our market;
- lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, whistleblower or other claims;
- the announcement of new products or product enhancements by us or our competitors;
- announced or completed acquisitions of businesses or technologies by us or our competitors;

- developments in our industry; and
- other factors described in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. We will remain an “emerging growth company” until the earliest to occur of:

- the last day of the fiscal year during which our total annual revenue equals or exceeds \$1.235 billion (subject to adjustment for inflation);
- December 31, 2030;
- the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt; or
- the date on which we are deemed to be a “large accelerated filer” under the Exchange Act.

As a result of our “emerging growth company” status, we may take advantage of exemptions from various reporting requirements that would otherwise be applicable to public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be adversely affected and more volatile.

We incur increased costs and are subject to additional regulations and requirements as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we incur significant legal, accounting and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We have also incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and the listing requirements of the Nasdaq Global Select Market. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs

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and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

If we are unable to design, implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second annual report on Form 10-K, we will be required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to the rules and regulations of the SEC regarding compliance with Section 404 of the Sarbanes-Oxley Act. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. We have in the past and may in the future identify control deficiencies, including material weaknesses in our internal control over financial reporting. In connection with the preparation of our consolidated financial statements, material weaknesses in our internal control over financial reporting were identified as of and prior to December 31, 2023, which were remediated in connection with the preparation of our consolidated financial statements as of and for the year ended December 31, 2024. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. Further, if we identify one or more material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or if we and, if required, our auditors, are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably ensure that information required to be disclosed by us in reports

we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that our disclosure controls and procedures as well as internal control over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are and will be met. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of October 31, 2025, our executive officers, directors, owners of more than 5% of our capital stock and their respective affiliates beneficially owned approximately 40.9% of our outstanding shares. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, and any sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up agreements, market standoff and other legal restrictions on resale in place at the time of the IPO lapse, the trading price of our common stock could decline and such decline may be significant. As of October 31, 2025, we had outstanding a total of 85,158,719 shares of common stock. Of these shares, all of the shares of our common stock sold in our IPO, were freely tradable, without restriction, in the public market immediately following our IPO, other than shares purchased by our "affiliates" (as such term is defined in Rule 144 under the Securities Act).

We and each of our directors, our executive officers and substantially all of our other securityholders have entered into lock-up agreements with the underwriters prior to the completion of our IPO or are subject to market standoff arrangements for a period of 180 days commencing on the date of our IPO. After the expiration of the lock-up agreements and market standoff arrangements, as of October 31, 2025, up to approximately 66.0 million additional shares of common stock will be eligible for sale in the public market, approximately 47.6% of which shares are owned by directors, executive officers and other owners of more than 5% of our outstanding common stock, stock options, warrants and securities convertible into our common stock and will be subject to Rule 144 under the Securities Act.

Based upon the number of shares outstanding as of October 31, 2025, the holders of approximately 55.8 million shares of our common stock, or approximately 66% of our total outstanding common stock, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the

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lock-up agreements and market standoff restrictions described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders or

any perception that these shares may be sold could reduce the market price of our common stock, which price decline may be significant. In addition, a security holder who is not subject to market standoff restrictions with us nor a lock-up agreement with the underwriters may be able to sell, short sell, transfer, pledge or otherwise dispose of their equity interests at any time.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if such court does not have jurisdiction, Delaware federal district court) is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) are the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers, employees or stockholders to us or to our stockholders, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time) or as to which the Delaware General Corporation Law confers jurisdiction on the Delaware Court of Chancery, or any action asserting a claim against us that is governed by the internal affairs doctrine of the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States is the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Further, our amended and restated certificate of incorporation provides that the foregoing choice of forum provisions do not apply to suits brought to enforce any liability or duty created by the Exchange Act, or any other claim for which the federal courts of the United States have exclusive jurisdiction.

Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the foregoing provisions of the amended and restated certificate of incorporation. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums, and protection against the burdens of multi-forum litigation. However, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such

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action in other jurisdictions, which could adversely affect our business, financial condition, results of operations and prospects.

General Risk Factors

We have broad discretion in the use of net proceeds to us from our IPO and may not use them effectively.

In connection with the completion of our IPO, we were obligated to use certain of the net proceeds from our IPO to repay \$55.0 million of the indebtedness outstanding under the 2024 Credit Agreement and to pay approximately \$5.8 million of fees in connection therewith. In addition, in August 2025, we prepaid in full all remaining outstanding indebtedness, comprising an aggregate principal amount of \$60.1 million plus accrued interest of \$1.0 million, under the 2024 Credit Agreement. We expect to use the remainder to fund 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. We may also use a portion of the net proceeds from our IPO to acquire complementary businesses, products, services, or technologies.

We periodically evaluate strategic opportunities; however, we have no current understandings or commitments to enter into any such acquisitions or make any such investments. The expected use of our IPO net proceeds represents our intentions based upon our present plans and business conditions. We cannot predict with certainty all of the particular uses for the proceeds from our IPO or the amounts that we will actually spend on the uses set forth above. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business.

If we do not use the net proceeds that we received from our IPO effectively, our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline. Pending their use, we are investing our IPO net proceeds in a variety of capital-preservation investments, including government securities and money market funds. These investments may not yield a favorable return to our investors.

We do not intend to pay dividends in the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determinations regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable law, and will depend upon then-existing conditions, including our financial condition, results of operations, contractual restrictions, general business conditions, capital requirements, and other factors our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to the risks and uncertainties described in this Quarterly Report on Form 10-Q, including in the section titled "Risk Factors" and in our future public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If actual circumstances differ from those in our assumptions, our operating and financial results could fall below our publicly announced guidance or the expectations of investors. If, in the future, our operating or financial results for a particular period do not meet any guidance we provide or the expectations of investment analysts or investors generally, or if we reduce our guidance for future periods, the market

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price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, or if they cease coverage of us or fail to publish reports on us regularly, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. We do not control these analysts. If any of the analysts who cover us downgrade their evaluations of our stock or issue an adverse opinion regarding us, our business model, our intellectual property or our stock performance, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, following periods of volatility in the overall market and the market price of a company's securities, securities class action litigation has often been instituted against these companies. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources, which could seriously harm our business.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- our directors may be removed by our stockholders only for cause;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to change the size of the board of directors and to elect a director to fill a new directorship created by the expansion of the board of directors or a vacancy created by the resignation, death or removal of a director, which prevents stockholders from being able to change the board's size or fill new directorships and vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer or adopt a stockholder rights plan;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all then-outstanding shares of capital stock entitled to vote generally in the election of directors to remove directors or to adopt, amend, alter or repeal our amended and restated bylaws and certain provisions of our amended and restated certificate of incorporation;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our secretary at the request of our board of directors, the chairman of our board of directors, or our chief executive officer, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law ("Section 203"). Under Section 203, a corporation may not, in general, engage in a business combination (as defined in Section 203) with any interested stockholder (generally defined by Section 203 to include holders of 15% or more of our capital stock) unless the interested stockholder has held the stock for three years or, among other exceptions and exclusions, the board of directors has approved the business combination transaction or the transaction that resulted in the stockholder becoming an interested stockholder.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sale of Equity Securities

None.

Use of Proceeds

For a discussion of the use of proceeds from our IPO, see the information in Part II, Item 2, "Use of Proceeds" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025. There have been no material changes to the use of proceeds from our IPO disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Insider Trading Arrangements

During the quarter ended September 30, 2025, three of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a "Rule 10b5-1 (c) trading arrangement" or a "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(a) of Regulation S-K as follows:

On September 12, 2025, John C.M. Farquhar, our President and Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 427,900 shares of our common stock. The duration of the trading arrangement is until January 11, 2027, or earlier if all transactions under the trading arrangement are completed. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c).

On September 12, 2025, Campbell D.K. Rogers, M.D., our Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 254,144 shares of

our common stock. The duration of the trading arrangement is until April 2, 2026, or earlier if all transactions under the trading arrangement are completed. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c).

On September 12, 2025, Julie A. Cullivan, one of our directors, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 17,122 shares of our common stock. The duration of the trading arrangement is until March 27, 2026, or earlier if all transactions under the trading arrangement are completed. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c).

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Item 6. Exhibit Index

The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference, into this Quarterly Report on Form 10-Q.

Exhibit number	Exhibit description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-42790	3.1	8/11/2025
3.2	Amended and Restated Bylaws.	8-K	001-42790	3.2	8/11/2025
10.1#	Heartflow, Inc. 2025 Performance Incentive Plan.	S-1	333-288733	10.2	7/17/2025
10.2#	Heartflow, Inc. 2025 Performance Incentive Plan Form of Option Agreement (Employee).	10-Q	001-42790	10.3	9/19/2025
10.3#	Heartflow, Inc. 2025 Performance Incentive Plan Form of Option Agreement (Director).	10-Q	001-42790	10.4	9/19/2025
10.4#	Heartflow, Inc. 2025 Performance Incentive Plan Form of Restricted Stock Unit Agreement.	10-Q	001-42790	10.5	9/19/2025
10.5#	Heartflow, Inc. 2025 Employee Stock Purchase Plan.	S-1	333-288733	10.3	7/17/2025
10.6#	Heartflow, Inc. Senior Leadership Severance Policy.	S-1	333-288733	10.4	7/17/2025
10.7#	Heartflow, Inc. Director Compensation Policy.	10-Q	001-42790	10.8	9/19/2025
31.1+	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2+	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS+	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH+	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.				
104+	Cover Page Interactive Data File (embedded within the Inline XBRL document).				

Indicates management contract or compensatory plan.

+ Filed herewith.

* The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HEARTFLOW, INC.

Date: November 12, 2025

By: /s/ John C.M. Farquhar
John C.M. Farquhar
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2025

By: /s/ Vikram Verghese
Vikram Verghese
Chief Financial Officer
(Principal Financial Officer)

Date: November 12, 2025

By: /s/ Mhairi L. Jones
Mhairi L. Jones
Chief Accounting Officer and VP
(Principal Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John C.M. Farquhar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Heartflow, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. [Omitted];
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2025

By: /s/ John C.M. Farquhar
John C.M. Farquhar
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Vikram Verghese, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Heartflow, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. [Omitted];
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2025

By: /s/ Vikram Verghese
Vikram Verghese
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Heartflow, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify that, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2025

By: /s/ John C.M. Farquhar
John C.M. Farquhar
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Heartflow, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify that, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2025

By: /s/ Vikram Verghese
Vikram Verghese
Chief Financial Officer
(Principal Financial Officer)