

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, 2024
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: 001-39949

Hyperfine, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

98-1569027

(IRS Employer
Identification No.)

351 New Whitfield Street
Guilford, Connecticut

(Address of principal executive offices)

06437

(Zip Code)

(866) 796-6767

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, \$0.0001 Par Value Per Share	HYPR	The Nasdaq Stock Market LLC

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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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 Exchange Act). Yes ☐ No ☒

As of November 1, 2024, the registrant had 57,893,458 shares of Class A common stock outstanding and 15,055,288 shares of Class B common stock outstanding.

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All brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners. Unless the context requires otherwise, references in this report to the "Company," "we," "us," and "our" refer to Hyperfine, Inc. and its wholly-owned subsidiaries, including Hyperfine Operations, Inc., ("Legacy Hyperfine"), and Liminal Sciences, Inc., ("Liminal"), as the case may be.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that relate to future events or our future financial performance regarding, among other things, the plans, strategies and prospects, both business and financial, of the Company. These statements are based on the beliefs and assumptions of our management team. Although we believe that our plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure you that we will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, are forward-looking statements. These statements may be preceded by, followed by or include the words "believes," "estimates," "expects," "projects," "forecasts," "may," "will," "should," "seeks," "plans," "scheduled," "anticipates" or "intends" or similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing of our product development activities;
- the commercialization and adoption of our existing products and the success of our future product offerings, including the degree to which our products and services are accepted and used by healthcare professionals;
- the potential attributes and benefits of our products and services, including the clinical evidence supporting those benefits, and our ability to generate clinical evidence of the benefits of our products and services;
- our ability to obtain and maintain regulatory approval for our products, and any related restrictions and limitations of any cleared or approved product;
- our intellectual property rights;
- our ability to identify, in-license or acquire additional technology;
- our ability to maintain our existing or future licensing, manufacturing and supply agreements and to obtain adequate supply of products;
- our ability to compete with other companies currently marketing or engaged in the development of magnetic resonance imaging technologies, many of which have greater financial and marketing resources than us;
- the size and growth potential of the markets for our products and services, and the ability of our products and services to serve those markets, either alone or in partnership with others;
- our expansion plans and our ability to grow and manage growth profitably;
- the pricing of our products and services and reimbursement for medical procedures conducted using our products and services;
- changes in applicable laws or regulations;
- our estimates regarding expenses, revenue, capital requirements, cash runway, and needs for additional financing;
- our ability to raise financing in the future;
- our future performance, including our financial performance;
- our success in retaining or recruiting, or necessary changes in, our officers, key employees or directors;
- intense competition and competitive pressures from other companies in the industry in which we operate;

- market conditions and global and economic factors, such as inflation and geopolitical conflicts and instability; and
- the effect of legal, tax and regulatory changes.

These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the “2023 Annual Report on Form 10-K”), filed with the Securities and Exchange Commission (the “SEC”) on March 22, 2024, as updated and/or supplemented in subsequent filings with the SEC. The risks described under the heading “Risk Factors” are not exhaustive. New risk factors emerge from time to time, and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. All forward-looking statements attributable to the Company or persons acting on its behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 45,765	\$ 75,183
Restricted cash	219	621
Accounts receivable, less allowance of \$482 and \$321 as of September 30, 2024 and December 31, 2023, respectively	6,800	3,189
Unbilled receivables	2,264	942
Inventory	7,044	6,582
Prepaid expenses and other current assets	2,002	2,391
Total current assets	64,094	88,908
Property and equipment, net	3,125	2,999
Other long term assets	2,167	2,292
Total assets	\$ 69,386	\$ 94,199
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,404	\$ 1,214
Deferred grant funding	219	621
Deferred revenue	1,413	1,453
Due to related parties	53	61
Accrued expenses and other current liabilities	6,870	5,419
Total current liabilities	9,959	8,768
Long term deferred revenue	1,105	968
Other noncurrent liabilities	—	64
Total liabilities	11,064	9,800
COMMITMENTS AND CONTINGENCIES (NOTE 13)		
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 57,893,458 and 56,840,949 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	5	5
Class B Common stock, \$.0001 par value; 27,000,000 shares authorized; 15,055,288 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	342,367	338,114
Accumulated deficit	(284,052)	(253,722)
Total stockholders' equity	58,322	84,399
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 69,386	\$ 94,199

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

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sales				
Device	\$ 3,033	\$ 1,728	\$ 8,707	\$ 6,670
Service	610	602	1,862	1,676
Total sales	3,643	2,330	10,569	8,346
Cost of sales				
Device	1,359	835	4,280	3,321
Service	376	371	1,224	1,302
Total cost of sales	1,735	1,206	5,504	4,623
Gross margin	1,908	1,124	5,065	3,723
Operating Expenses:				
Research and development	5,865	5,739	17,394	16,531
General and administrative	4,510	4,615	13,361	16,103
Sales and marketing	2,496	2,529	6,769	7,575
Total operating expenses	12,871	12,883	37,524	40,209
Loss from operations	(10,963)	(11,759)	(32,459)	(36,486)
Interest income	585	1,021	2,056	2,920
Other income (expense), net	52	(19)	73	12
Loss before provision for income taxes	(10,326)	(10,757)	(30,330)	(33,554)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (10,326)	\$ (10,757)	\$ (30,330)	\$ (33,554)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.14)	\$ (0.15)	\$ (0.42)	\$ (0.47)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	72,678,622	71,464,315	72,219,681	71,178,769

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

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)
(in thousands, except share amounts)

	Class A Common Stock		Class B Common Stock		Additional		Accumulated		Total	
	Shares	Amount	Shares	Amount	Paid-in Capital		Deficit		Stockholders' Equity	
Balance, December 31, 2023	56,840,989	\$ 5	15,055,288	\$ 2	\$ 338,114		\$ (253,722)		\$ 84,399	
Net loss	—	—	—	—	—		(9,848)		(9,848)	
Issuance of restricted stock	41,007	—	—	—	—		—		—	
Exercise of stock options	70,670	—	—	—	55		—		55	
Stock-based compensation expense	—	—	—	—	1,032		—		1,032	
Balance, March 31, 2024	56,952,666	5	15,055,288	2	339,201		(263,570)		75,638	
Net loss	—	—	—	—	—		(10,156)		(10,156)	
Issuance of restricted stock	34,915	—	—	—	—		—		—	
Exercise of stock options	144,121	—	—	—	105		—		105	
Stock-based compensation expense	—	—	—	—	1,174		—		1,174	
Balance, June 30, 2024	57,131,702	\$ 5	15,055,288	\$ 2	\$ 340,480		\$ (273,726)		\$ 66,761	
Net loss	—	—	—	—	—		(10,326)		(10,326)	
Shares issued under "at-the-market" (ATM) offering program, net	728,188	—	—	—	785		—		785	
Issuance of restricted stock	33,568	—	—	—	(1)		—		(1)	
Stock-based compensation expense	—	—	—	—	1,103		—		1,103	
Balance, September 30, 2024	57,893,458	\$ 5	15,055,288	\$ 2	\$ 342,367		\$ (284,052)		\$ 58,322	

	Class A Common Stock		Class B Common Stock		Additional		Accumulated		Total	
	Shares	Amount	Shares	Amount	Paid-in Capital		Deficit		Stockholders' Equity	
Balance, December 31, 2022	55,622,488	\$ 5	15,055,288	\$ 2	\$ 333,199		\$ (209,484)		\$ 123,722	
Net loss	—	—	—	—	—		(12,160)		(12,160)	
Issuance of restricted stock	324,296	—	—	—	—		—		—	
Exercise of stock options	54,211	—	—	—	49		—		49	
Stock-based compensation expense	—	—	—	—	1,126		—		1,126	
Balance, March 31, 2023	56,000,995	5	15,055,288	2	334,374		(221,644)		112,737	
Net loss	—	—	—	—	—		(10,637)		(10,637)	
Issuance of restricted stock	219,887	—	—	—	—		—		—	
Exercise of stock options	63,656	—	—	—	58		—		58	
Stock-based compensation expense	—	—	—	—	1,133		—		1,133	
Balance, June 30, 2023	56,284,538	\$ 5	15,055,288	\$ 2	\$ 335,565		\$ (232,281)		\$ 103,291	
Net loss	—	—	—	—	—		(10,757)		(10,757)	
Issuance of restricted stock	210,488	—	—	—	—		—		—	
Exercise of stock options	42,920	—	—	—	39		—		39	
Stock-based compensation expense	—	—	—	—	1,194		—		1,194	
Balance, September 30, 2023	56,537,946	\$ 5	15,055,288	\$ 2	\$ 336,798		\$ (243,038)		\$ 93,767	

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

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (30,330)	\$ (33,554)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	775	791
Stock-based compensation expense	3,308	3,453
Loss on disposal of property and equipment, net	156	48
Other	6	25
Changes in assets and liabilities:		
Accounts receivable, net	(3,611)	(334)
Unbilled receivables	(1,322)	(228)
Inventory	(579)	(2,494)
Prepaid expenses and other current assets	(324)	1,010
Due from related parties	—	48
Prepaid inventory	693	281
Other long term assets	(9)	142
Accounts payable	193	229
Deferred grant funding	(402)	(196)
Deferred revenue	97	(364)
Due to related parties	(8)	48
Accrued expenses and other current liabilities	949	(776)
Operating lease liabilities, net	(2)	—
Net cash used in operating activities	(30,410)	(31,871)
Cash flows from investing activities:		
Purchases of property and equipment	(375)	(546)
Net cash used in investing activities	(375)	(546)
Cash flows from financing activities:		
Proceeds from exercise of stock options	160	146
Proceeds from shares issued under “at-the-market” offering program, net of selling costs	805	—
Net cash provided by financing activities	965	146
Net decrease in cash and cash equivalents and restricted cash	(29,820)	(32,271)
Cash, cash equivalents and restricted cash, beginning of period	75,804	118,243
Cash, cash equivalents and restricted cash, end of period	45,984	85,972
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	45,765	85,424
Restricted cash	219	548
Total cash, cash equivalents and restricted cash	\$ 45,984	\$ 85,972
Supplemental disclosure of noncash information:		
Unpaid purchase of property and equipment	\$ 571	\$ 54

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

HYPERFINE, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(all amounts are in thousands, except share and per share amounts)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Hyperfine, Inc. (together with its subsidiaries, as applicable, "Hyperfine" or the "Company"), formerly known as HealthCor Catalio Acquisition Corp. ("HealthCor"), was incorporated as a Cayman Islands exempted company on November 18, 2020. The Company's legal name became Hyperfine, Inc. in connection with the closing (the "Closing") of the business combination with HealthCor (the "Business Combination") on December 22, 2021 (the "Closing Date"). In connection with the Closing, Hyperfine, Inc., a Delaware corporation ("Legacy Hyperfine"), and Liminal Sciences, Inc., a Delaware corporation ("Liminal"), merged with and into separate wholly owned subsidiaries of HealthCor and became wholly-owned subsidiaries of the Company (the "Mergers"), and changed their names to Hyperfine Operations, Inc. and Liminal Operations, Inc., respectively. Liminal subsequently changed its name to Liminal Sciences, Inc.

The Company is an innovative health technology business with a mission to revolutionize patient care globally through accessible, affordable, clinically relevant, portable ultra-low-field ("ULF") magnetic resonance ("MR") brain imaging. The Swoop® Portable MR Imaging® System ("Swoop® system") produces high-quality, diagnostic images at a lower magnetic field strength than conventional magnetic resonance imaging ("MRI") scanners. The Swoop® system is designed to transform brain MR for the patient, the clinician and the provider, providing a highly differentiated experience for patients, timely imaging to clinicians, and favorable economics for hospital administrators. The Swoop® system is a portable, ULF MRI device for producing images that display the internal structures of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. Healthcare professionals can use the Swoop® system to make effective clinical diagnoses and decisions in various care settings where conventional MRI devices are inaccessible at the point of care in professional health care facilities such as emergency rooms, intensive care units, hospitals, outpatient clinics and physician offices, or rehabilitation centers. The easy-to-use interface and portable design of the Company's Swoop® system make it easily and readily accessible anywhere in a hospital, clinic, or patient care site and it does not require any special facilities accommodations nor specialized personnel to operate safely. ULF MR does not expose patients to harmful ionizing radiation and compares favorably in this regard to X-ray computed tomography ("CT") or positron emission tomography ("PET").

The Company's Swoop® system received initial 510(k) clearance for brain imaging from the U.S. Food and Drug Administration ("FDA") in 2020. In February and October 2023, the Company received 510(k) clearances from the FDA for its Swoop® system AI-powered software. The combination of these two software updates significantly improved diffusion-weighted imaging ("DWI"), incorporated deep-learning based denoising in the post-processing of DWI images for crisper images, and improved image quality for all Swoop® system sequences. In July 2024, the Company received 510(k) clearance from the FDA of the ninth-generation AI-powered Swoop® system software. This software update significantly reduces scan times across multiple MR sequences without sacrificing image quality. Outside of the United States, the Swoop® system has received marketing authorization for brain imaging in several countries, including the European Union (CE certification), the United Kingdom (UK Conformity Assessment ("UKCA")), Canada, Australia and New Zealand. In October 2024, the Company received CE approval for the latest generation of software. All of the Company's revenue to date has been generated from sales of the Swoop® system and related services. The Company has an indirect wholly-owned subsidiary in the United Kingdom that did not have any significant operations during 2023 nor during the nine months ended September 30, 2024.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The unaudited accompanying condensed consolidated financial statements include the accounts of the Company and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the accounting disclosure rules and regulations of the SEC. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been

HYPERFINE, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(all amounts are in thousands, except share and per share amounts)

condensed or omitted pursuant to such rules and regulations. All intercompany transactions and balances have been eliminated.

These condensed consolidated financial statements should be read in conjunction with the financial statements and notes included in the Company's audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022. The condensed consolidated balance sheet as of December 31, 2023 included herein was derived from the audited consolidated financial statements as of that date.

The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for any subsequent quarter, the year ending December 31, 2024, or any other period.

Except as described elsewhere in this Note 2 under the heading "Recently Issued Accounting Pronouncements," there have been no material changes to the Company's significant accounting policies as described in the audited consolidated financial statements as of December 31, 2023 and 2022.

Risks and Uncertainties

The Company is subject to risks and uncertainties caused by events with significant geopolitical and macroeconomic impacts, including, but not limited to, the conflicts in Ukraine and the Middle East, inflation and actions taken to counter such impacts. The Company relies on a single source manufacturer and single source suppliers for the supply of its products. Disruption from the manufacturer or suppliers has and would have a negative impact on the Company's business, financial position and results of operations in its consolidated financial statements. The Company continues to critically review its liquidity and anticipated capital requirements in light of the significant uncertainty created by geopolitical and macroeconomic conditions.

Concentrations of Credit Risk

The Company's cash and cash equivalents are deposited with several major financial institutions. At times, deposits in these institutions exceed the amount of insurance provided on such deposits. The Company reduces this risk by maintaining such deposits with high quality financial institutions that management believes are creditworthy and the Company monitors this credit risk and makes adjustments to the concentrations as necessary. The Company has not experienced any losses in such accounts and does not believe that it is exposed to any significant risk of loss on these balances.

With respect to accounts receivable, credit risk is mitigated by the Company's ongoing credit evaluation of its customers' financial condition. As of September 30, 2024 and December 31, 2023, the Company had two customers and four customers, respectively, that each accounted for more than 10% of trade receivables. With respect to revenue, two and one customers each accounted for more than 10% of revenue for the three and nine months ended September 30, 2024, respectively. Two customers each accounted for more than 10% of revenue for each of the three and nine months ended September 30, 2023.

Segment Information

The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer ("CEO"). Substantially all of the Company's long-lived assets are located in the United States. Other than revenue recognized in non-U.S. countries of \$1,156 and \$5,254 for the three and nine months ended September 30, 2024, respectively, and \$65 and \$3,764 for the three and nine months ended September 30, 2023, respectively, all of the revenues during these periods were earned in the United States. Since the Company is aggregated into a single reportable segment, all required financial segment information is provided in the condensed consolidated financial statements.

HYPERFINE, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(all amounts are in thousands, except share and per share amounts)

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions about future events that affect the amounts reported in its condensed consolidated financial statements and accompanying notes. Future events and their effects cannot be determined with certainty. On an ongoing basis, management evaluates these estimates and assumptions. Significant estimates and assumptions included:

- Revenue recognition, including determination of the timing and pattern of satisfaction of performance obligations, determination of the standalone selling price ("SSP") of performance obligations;
- Allowance for credit losses;
- Net realizable value (the selling price as well as estimated costs of disposal and transportation) of inventory, and demand and future use of inventory;
- Valuation allowances with respect to deferred tax assets; and
- Assumptions underlying the fair value used in the calculation of stock-based compensation expense.

The Company bases these estimates on historical and anticipated results and trends and on various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates, and any such differences may be material to the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In March 2024, the SEC issued final rules under SEC Release No. 33-11275, The Enhancement and Standardization of Climate-Related Disclosures for Investors. Effective fiscal year 2026, the Company is required to disclose climate-related risks that are reasonably likely to have a material impact on the Company's business strategy, results of operations, or financial condition. Additionally, the Company will be required to disclose the effects of severe weather events and other natural conditions within the notes to the financial statements, subject to certain materiality thresholds. Effective fiscal year 2027, required disclosures will also include disclosure of material direct greenhouse gas emissions from operations owned or controlled (Scope 1) and material indirect greenhouse gas emissions from purchased energy consumed in owned or controlled operations (Scope 2). In April 2024, the SEC issued an order voluntarily staying the effectiveness of the new rules pending the completion of judicial review of certain legal challenges to their validity. The Company is currently evaluating the impact of these rules assuming adoption as well as monitoring the status of the related litigation and the SEC's stay.

In March 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-02, Codification Improvements-Amendments to Remove References to the Concepts Statements. The ASU contains amendments to the ASC that remove references to various FASB Concepts Statements. This update is effective for annual periods beginning after December 15, 2024, though early adoption is permitted. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements or disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances effective tax rate reconciliation disclosure requirements and provides clarity to the disclosures of income taxes paid, income before taxes and provision for income taxes. The amendments are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The amendments in this update should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating this ASU to determine the impact of the amendments on the Company's consolidated financial statements and disclosures.

HYPERFINE, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(all amounts are in thousands, except share and per share amounts)

In November 2023, the FASB issued ASU No. 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." This ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. This ASU is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2024, and subsequent interim periods, with early application permitted. The Company will be adopting the annual disclosure requirements of this ASU in its Annual Report Form 10-K for the fiscal year ending December 31, 2024.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC have not had, or are not believed by management to have, a material impact on the Company's present or future financial statements.

3. REVENUE RECOGNITION

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by product type. The Company believes that these categories best represent the payor types by nature, amount, timing and uncertainty of its revenue streams. The following table summarizes the Company's disaggregated revenues:

	Pattern of Recognition	Three Months Ended September 30,		Nine Months Ended September 30,	
		2024	2023	2024	2023
Device	Point in time	\$ 3,033	\$ 1,728	\$ 8,707	\$ 6,670
Service		610	602		
	Over time			1,862	1,676
Total revenue		\$ 3,643	\$ 2,330	\$ 10,569	\$ 8,346

Contract Balances

Contract balances represent amounts presented in the condensed consolidated balance sheets when either the Company has transferred goods or services to the customer, or the customer has paid consideration to the Company under the contract. These contract balances include trade accounts receivable and deferred revenue. Deferred revenue represents consideration received from customers at the beginning of the subscription period for services that are transferred to the customer over the respective subscription period. The accounts receivable balances represent amounts billed to customers for goods and services where the Company has an unconditional right to payment of the amount billed.

The following table provides information about receivables and deferred revenue from contracts with customers:

	September 30, 2024	December 31, 2023
Accounts receivable, net	\$ 6,800	\$ 3,189
Unbilled receivables - current	\$ 2,264	\$ 942
Unbilled receivables - non-current ⁽¹⁾	\$ 1,119	\$ 1,044
Deferred revenue	\$ 1,413	\$ 1,453
Long term deferred revenue	\$ 1,105	\$ 968

(1) Recorded in other long term assets in the Company's consolidated balance sheets. Unbilled receivables - non-current is based on the billing schedules for future billings beyond one year.

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The Company recognizes a receivable when it has an unconditional right to payment. Typical payment terms require the Company's customers to pay the Company within 30 days of invoice and up to less than one year based on the terms agreed upon with the respective customer.

Accounts Receivable, Unbilled Services, and Deferred Revenue

Accounts receivable are recorded at net realizable value. Unbilled receivables arise when performance obligations are satisfied for which revenue has been recognized but the customers have not been billed. Contractual provisions and payment schedules may or may not correspond to the timing of the performance of services under the contract.

Deferred revenue is a contract liability that consists of customer payments received in advance of performance and billings in excess of revenue recognized, net of revenue recognized from the balance at the beginning of the period.

The amount of revenue recognized during the three and nine months ended September 30, 2024 that was included in the deferred revenue balance at the beginning of the period was \$475 and \$1,172, respectively.

The amount of revenue recognized during the three and nine months ended September 30, 2023 that was included in the deferred revenue balance at the beginning of the period was \$477 and \$1,119, respectively.

Timing of Billing and Performance

Difference in the timing of revenue recognition and associated billings and cash collections result in recording of billed accounts receivable, unbilled accounts receivable (including contract assets), and deferred revenue on the consolidated balance sheet. Amounts are billed in accordance with the agreed-upon contractual terms, resulting in recording unbilled accounts receivable in instances where the right to bill is contingent solely on the passage of time, and contract assets in instances where the right to consideration is conditional on something other than the passage of time.

Revenue from Leasing Arrangements

Revenue from leasing arrangements is not subject to the revenue standard for contracts with customers and remains separately accounted for under ASC 842, including leases for the three and nine months ended September 30, 2024 and 2023. The Company recorded service revenue from lease arrangements of \$44 and \$203 for the three and nine months ended September 30, 2024, respectively. The Company recorded service revenue from lease arrangements of \$100 and \$329 for the three and nine months ended September 30, 2023, respectively. The Company records revenue from the sale of hardware devices under sales-type leases as device revenue in an amount equal to the present value of minimum lease payments at the inception of the lease. Sales-type leases also produce financing income, which is included in device revenue in the consolidated statements of operations and comprehensive loss and is recognized at effective rates of return over the lease term.

Costs of Obtaining or Fulfilling Contracts

The Company incurs incremental costs of obtaining contracts with customers. Incremental costs of obtaining contracts, which include commissions paid as a result of obtaining contracts with customers, are capitalized to the extent that the Company expects to recover such costs. Capitalized costs are amortized in a pattern that is consistent with the Company's transfer to the customer of the related goods and services. Such costs are recorded in Other long term assets and were \$480 and \$391 as of September 30, 2024 and December 31, 2023, respectively. During the three and nine months ended September 30, 2024, the Company recognized \$408 and \$814, respectively, in expense related to the amortization of the capitalized contract costs. During the three and nine months ended September 30, 2023, the Company recognized \$205 and \$331, respectively, in expense related to the amortization of the capitalized contract costs.

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Transaction price allocated to remaining performance obligations

As of September 30, 2024 and December 31, 2023, the Company had remaining performance obligations amounting to \$5,682 and \$5,661, respectively. The Company expects to recognize approximately 10% of its remaining performance obligations as revenue in fiscal year 2024, and an additional 90% in fiscal year 2025 and thereafter.

4. FAIR VALUE OF FINANCIAL INSTRUMENTS

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair value.

The Company measures fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The Company utilizes a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 — Valuations based on quoted prices in active markets for identical assets or liabilities that an entity has the ability to access.

Level 2 — Valuations based on quoted prices for similar assets or liabilities, quoted prices for identical assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3 — Valuations based on inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company has no assets or liabilities valued with Level 3 inputs.

The carrying value of cash and cash equivalents, accounts payable and accrued expenses and other current liabilities approximates their fair values due to the short-term or on demand nature of these instruments.

The Company had no assets or liabilities classified as Level 2 or Level 3 and there were no transfers between fair value measurement levels during the three and nine months ended September 30, 2024 or 2023.

The Company had \$45,764 and \$74,685 of money market funds, demand deposit and savings accounts included in cash and cash equivalents and restricted cash as of September 30, 2024 and December 31, 2023, respectively. These assets were valued using quoted prices in active markets and accordingly were classified as Level 1.

5. INVENTORIES

A summary of inventories is as follows:

	September 30, 2024	December 31, 2023
Raw materials	\$ 3,419	\$ 1,757
Finished goods	3,625	4,825
Total inventories	\$ 7,044	\$ 6,582

Manufacturing overhead costs primarily include management's best estimate and allocation of the labor costs incurred related to acquiring finished goods from the Company's contract manufacturer. Labor costs include wages, taxes and benefits for employees involved in warehousing, logistics coordination, material sourcing, and production planning activities.

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6. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, are recorded at historical cost and consist of the following:

	September 30, 2024	December 31, 2023
Laboratory equipment	\$ 986	\$ 986
Research devices	1,396	1,532
Sales and marketing devices	490	490
Computer equipment	689	668
Construction in progress	1,075	595
Tooling	832	505
Trade show assets	254	254
Leased devices	289	397
Other	586	611
	6,597	6,038
Less: Accumulated depreciation and amortization	(3,472)	(3,039)
Property and equipment, net	\$ 3,125	\$ 2,999

Depreciation expense amounted to \$259 and \$775 for the three and nine months ended September 30, 2024, respectively.

Depreciation expense amounted to \$278 and \$791 for the three and nine months ended September 30, 2023, respectively.

7. RIGHT-OF-USE ("ROU") ASSETS AND LEASES LIABILITIES

The Company has operating leases for its corporate offices, including its Palo Alto, California lease agreement which expires on April 30, 2025. As of September 30, 2024, the Palo Alto, California lease had an operating lease ROU assets of \$105, current lease liabilities of \$113, which are included in the Company's condensed consolidated balance sheets in other long term assets, accrued expenses and other current liabilities.

The weighted-average remaining lease term associated with the measurement of the Company's operating lease obligations is 7 months and the weighted-average discount rate is 7.9%.

The Company recorded short-term operating lease cost during the three and nine months ended September 30, 2024 of \$45 and \$134, respectively. Cash paid for operating lease during the three and nine months ended September 30, 2024 was \$50 and \$147, respectively.

Future minimum commitments due under the lease agreement as of September 30, 2024 are \$50 for the remainder of 2024 and \$66 thereafter.

On March 1, 2024, the Company entered into a lease agreement for approximately 10,000 square feet of warehouse space in Guilford, Connecticut. The lease term is 12 months beginning March 1, 2024, and includes an option to renew for an additional one-year term at the then prevailing rental rate. The exercise of the lease renewal option is at the Company's sole discretion. The Company applied the practical expedient, which allows entities with leases of 12 months or shorter to not recognize ROU assets and lease liabilities for short-term leases. Future minimum commitments due under the lease agreement as of September 30, 2024 are \$17 for the remainder of 2024 and \$12 thereafter.

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8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

	September 30, 2024	December 31, 2023
Bonuses	\$ 2,182	\$ 2,463
Contracted services	2,248	1,237
Legal fees	562	412
Payroll and related benefits	1,117	676
Operating lease liabilities	113	185
Other	648	446
Total accrued expenses and other current liabilities	\$ 6,870	\$ 5,419

9. STOCKHOLDERS' EQUITY

Common Stock At-the-Market (ATM) Offering Program

On November 9, 2023, the Company filed a \$150,000 shelf registration statement on Form S-3, which became effective on November 22, 2023, and includes a prospectus (the "Sales Agreement Prospectus") covering up to an aggregate of \$50,000 in shares of Class A common stock that the Company may issue and sell from time to time, through B. Riley Securities, Inc. ("B. Riley") acting as its sales agent, pursuant to the sales agreement that the Company entered into with B. Riley in November 2023 (the "Sales Agreement"), for its "at-the-market" ("ATM") equity program. The shelf registration statement is effective for three years and permits the Company to sell, from time to time, up to \$150,000 in aggregate value of its Class A common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide the Company with flexibility to access additional capital when market conditions are appropriate.

As of the filing of the 2023 Annual Report on Form 10-K, the Company is subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its shelf registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of its common stock held by non-affiliates. Therefore, the Company is limited in the amount of proceeds it is able to raise by selling shares of its common stock using its Form S-3, including shares issued under the Sales Agreement, until such time as the Company's public float exceeds \$75 million. On March 22, 2024, the Company filed an amendment to the Sales Agreement Prospectus, pursuant to which, as of such date, the Company may offer and sell shares of its Class A common stock having an aggregate offering price of up to \$22,816,801 from time to time through or to B. Riley, acting as sales agent or principal. As of September 30, 2024 and during the three months ended September 30, 2024, a total of 728,188 shares of Class A common stock have been issued and sold under the Sales Agreement, for gross proceeds of \$836 and net proceeds of \$785, after deducting commissions and other offering expenses related to the ATM.

Equity Incentive Plan

The Company's 2021 Equity Incentive Plan (the "Plan") is administered by the Company's board of directors and its compensation committee, which may grant restricted stock units ("RSUs") and options to purchase shares either as incentive stock options or non-qualified stock options, and other stock-based awards. The option grants are subject to certain terms and conditions, option periods and conditions, exercise rights and privileges as set forth in the Plan.

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Stock option activity

The following table summarizes the changes in the Company's outstanding stock options for the nine months ended September 30, 2024:

	Number of Options
Outstanding at January 1, 2024	14,271,587
Granted ⁽¹⁾ ⁽²⁾	5,434,883
Exercised	(214,791)
Forfeited / Cancelled / Expired	(778,282)
Outstanding at September 30, 2024	<u>18,713,397</u>

(1) Includes new hire employee grants of stock options to purchase 628,600 shares of the Company's Class A common stock. Also includes annual employee grants of stock options and special employee grants of stock options to purchase 1,975,283 shares of the Company's Class A common stock, and grants to executive officers of stock options to purchase 2,435,000 shares of the Company's Class A common stock. The grants vest 25% on the first anniversary date of the grant with the remainder vesting equally over the remaining 36 months, subject to the employee's continued service to the Company through the applicable vesting dates.

(2) Includes the annual equity grants to each of the Company's five nonemployee directors of non-qualified stock options to purchase 79,200 shares of the Company's Class A common stock, effective as of June 12, 2024, for an aggregate of non-qualified stock options to purchase 396,000 shares of the Company's Class A common stock. The grants will vest on the date of the Company's next regular annual stockholders meeting, subject to the directors' continued service to the Company through the vesting date.

In general, employee awards will vest based on continued service, which is generally over four years. Nonemployee director awards generally will vest in one year based on continued service on the date of the next regular annual stockholders meeting. The grant date fair value of the award will be recognized as stock-based compensation expense over the requisite service period. The grant date fair value was determined using similar methods and assumptions as those previously disclosed by the Company.

Restricted stock unit activity

The following table summarizes the changes in the Company's outstanding RSUs for the nine months ended September 30, 2024:

	Number of RSUs
Outstanding at January 1, 2024	369,026
Granted	—
Vested	(110,041)
Forfeited	(34,136)
Outstanding at September 30, 2024	<u>224,849</u>

The following table presents details of stock-based compensation expenses by functional line item noted within the Company's operating expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of sales	\$ 18	\$ 26	\$ 66	\$ 77
Research and development	383	371	1,107	805
Sales and marketing	49	44	135	139
General and administrative	652	753	2,000	2,432
	<u>\$ 1,102</u>	<u>\$ 1,194</u>	<u>\$ 3,308</u>	<u>\$ 3,453</u>

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10. NET LOSS PER SHARE

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock of the Company outstanding during the period. Diluted net loss per share is computed by giving effect to all common equivalent shares of the Company, including outstanding stock options, RSUs and Earn-Out Shares (defined below), to the extent dilutive. Basic and diluted net loss per share was the same for each period presented as the inclusion of all common equivalent shares of the Company outstanding would have been anti-dilutive.

The following table presents the calculation of basic and diluted net loss per share for the Company's common stock:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net Loss	\$ (10,326)	\$ (10,757)	\$ (30,330)	\$ (33,554)
Numerator for Basic and Dilutive EPS – Loss available to common stockholders	\$ (10,326)	\$ (10,757)	\$ (30,330)	\$ (33,554)
Denominator:				
Common Stock	72,678,622	71,464,315	72,219,681	71,178,769
Denominator for Basic and Dilutive EPS - Weighted-average common stock	72,678,622	71,464,315	72,219,681	71,178,769
Basic and dilutive net loss per share	\$ (0.14)	\$ (0.15)	\$ (0.42)	\$ (0.47)

Since the Company was in a net loss position for all periods presented, net loss per share attributable to Class A and Class B common stockholders was the same on a basic and diluted basis, as the inclusion of all common equivalent shares outstanding would have been anti-dilutive. Anti-dilutive common equivalent shares were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Outstanding options to purchase common stock	18,713,397	14,654,235	18,713,397	14,654,235
Outstanding RSUs	224,849	686,515	224,849	686,515
Earn-Out Shares ⁽¹⁾	9,357,835	9,357,835	9,357,835	9,357,835
Total anti-dilutive common equivalent shares	28,296,081	24,698,585	28,296,081	24,698,585

(1) The Company will issue to holders of Legacy Hyperfine and Liminal securities as of immediately prior to the effective time of the Mergers, in accordance with their pro rata share, up to 10,000,000 shares of Class A common stock as earn-out consideration (the "Earn-Out Shares") net of forfeitures, if at any time during the period between the Closing Date of December 22, 2021 and the third anniversary of the Closing Date (the "Earn-Out Period"), (i) the last share price of the Class A common stock is greater than or equal to \$15.00 for any 20 trading days within any 30 consecutive trading day period, or (ii) there is a transaction that will result in shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value greater than or equal to \$15.00. During the Earn-Out Period, if there is a transaction (other than for stock splits, stock dividends, special cash dividends, reorganizations, recapitalizations or similar transactions affecting the Class A common stock) that will result in the shares of Class A common stock being converted or exchanged into the right to receive cash or other consideration having a value less than \$15.00, then the right to receive Earn-Out Shares will terminate.

11. INCOME TAXES

The Company accounts for income taxes under ASC 740, "Income Taxes" ("ASC 740"). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

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Income taxes for the three and nine months ended September 30, 2024 and 2023 are recorded at the Company's estimated annual effective income tax rate, subject to adjustments for discrete events, if they occur. The Company's estimated annual effective tax rate was 0.0% for the three and nine months ended September 30, 2024 and 2023. The primary reconciling items between the federal statutory rate of 21.0% for these periods and the Company's overall effective tax rate of 0.0% were related to the effects of deferred state income taxes, research and development credits, stock-based compensation, and the valuation allowance recorded against the full amount of its net deferred tax assets.

A valuation allowance is required when it is more likely than not that some portion or all of the Company's deferred tax assets will not be realized. The realization of deferred tax assets depends on the generation of sufficient future taxable income during the period in which the Company's related temporary differences become deductible. The Company has recorded a full valuation allowance against its net deferred tax assets as of September 30, 2024 and 2023 since management believes that based on the earnings history of the Company, it is more likely than not that the benefits of these assets will not be realized.

12. RELATED PARTY TRANSACTIONS

The Company utilizes and subleases office and lab space in Connecticut, which is being leased from an unrelated landlord by 4Catalyzer Corporation ("4C"), which is owned by a related party. The Company pays rent to 4C on a month-to-month basis. A total of approximately \$138 and \$386 was paid during the three and nine months ended September 30, 2024, respectively, and a total of approximately \$122 and \$285 was paid during the three and nine months ended September 30, 2023, respectively.

Hyperfine entered into a Master Services Agreement (the "Master Services Agreement") with 4C effective as of July 7, 2021 pursuant to which Hyperfine may engage 4C to provide services such as general administration, facilities, information technology, financing, legal, human resources and other services, through future statements of work and under terms and conditions to be determined by the parties with respect to any services to be provided. The Company paid an aggregate of \$33 and \$98 during the three and nine months ended September 30, 2024, respectively, and the Company paid an aggregate of \$29 and \$149 during the three and nine months ended September 30, 2023, respectively, under the Master Services Agreement. As of September 30, 2024 and December 31, 2023 there were \$53 and \$61 due to 4C, respectively, for expenses paid on the Company's behalf. These payables are included in due to related parties on the condensed consolidated balance sheet.

13. COMMITMENTS AND CONTINGENCIES

Commitments

The Company sponsors a 401(k) defined contribution plan covering all eligible U.S. employees. Contributions to the 401(k) plan are discretionary. The Company did not make any matching contributions to the 401(k) plan for the three and nine months ended September 30, 2024 or 2023.

During 2020 and 2021, the Company was awarded multiple grants totaling \$4,910 from the Bill & Melinda Gates Foundation ("BMGF") for the provision and equipping of sites with the Company's portable MR brain imaging system to enable the performance of a multi-site study focused on optimizing diagnostic image quality. These grants are designed to provide data to validate the use of the Swoop® system in measuring the impact of maternal anemia, malnutrition, infection and birth related injury. All of these grants are designed to support the deployment of a total of 25 Swoop® system devices and other services to investigators, which commenced in the spring of 2021 and was completed by February 2024. In May 2023, the Company was awarded an additional \$3,354 grant from the BMGF to continue to develop a scalable approach to measuring neurodevelopment via low-field MRI in neonates, infants, and young children in low-to-middle income countries through February 2026. The funds are accounted for as restricted cash with a corresponding credit to deferred grant funding. Any grant funds, plus any interest income, that have not been used for, or committed to, the project must be returned promptly to the BMGF upon expiration of or termination of the agreement. During the nine months ended September 30, 2024, the Company completed and fulfilled grant deliverables and milestones amounting to \$1,482 and received cash grant funding of \$1,122. As of September 30, 2024, the Company recorded restricted cash of \$219 with an offset to deferred grant funding in the

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Company's unaudited condensed consolidated balance sheet. As of September 30, 2024, and December 31, 2023, there were no grant fund amounts that were required to be returned under the terms of the project.

Purchase Commitments

The Company's purchase commitments and obligations include all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which the Company has not received the goods or services. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel, reschedule, and adjust its requirements based on the Company's business needs prior to the delivery of goods or performance of services.

Contingencies

The Company is, from time to time, a party to litigation that arises in the normal course of its business operations. The Company is not presently a party to any litigation for which it believes a loss is probable requiring an amount to be accrued or a possible loss contingency requiring disclosure.

The Company has indemnification obligations under some agreements that the Company enters into with other parties in the ordinary course of business, including business partners, investors, contractors, and the Company's officers, directors and certain employees. The Company has agreed to indemnify and defend the indemnified party against claims and related losses suffered or incurred by the indemnified party from actual or threatened third-party claims because of the Company's activities or non-compliance with certain representations and warranties made by the Company. It is not possible to determine the maximum potential loss under these indemnification provisions due to the Company's limited history of prior indemnification claims and the unique facts and circumstances involved in any particular case. The Company has not recorded any liability under such indemnification provisions within its condensed consolidated balance sheets. The Company is not aware of any claims or other circumstances that would give rise to material payments from the Company under such indemnification provisions.

The Company agreed to pay \$1,000 to a third-party service provider if the Company's pre-closing equity holders receive any Earn-Out Shares. As the Company has not met the criteria to trigger the earn-out, such payment is not determined to be probable and no liability was recognized within our condensed consolidated balance sheets. See Note 10. Net Loss Per Share, for further information regarding the earn-out criteria.

14. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date the condensed consolidated financial statements were issued and has determined that there were no subsequent events required to be disclosed.

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

The following discussion and analysis provides information which management believes is relevant to an assessment and understanding of our condensed consolidated results of operations and financial condition. The discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto contained in this Quarterly Report on Form 10-Q and the consolidated financial statements and notes thereto for the year ended December 31, 2023 contained in our 2023 Annual Report on Form 10-K. This discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" sections of our 2023 Annual Report on Form 10-K, as updated and/or supplemented in subsequent filings with the SEC. Actual results may differ materially from those contained in any forward-looking statements. Unless the context otherwise requires, references to "we," "us," "our," and "the Company" are intended to mean the business and operations of Hyperfine, Inc. and its consolidated subsidiaries. The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2024 and 2023, respectively, present the financial position and results of operations of Hyperfine, Inc. and its wholly owned subsidiaries.

Overview

We are an innovative health technology business with a mission to revolutionize patient care globally through accessible, affordable, clinically relevant, portable ultra-low-field ("ULF") magnetic resonance ("MR") brain imaging. Our Swoop® Portable MR Imaging® System ("Swoop® system") produces high-quality, diagnostic images at a lower magnetic field strength than conventional magnetic resonance imaging ("MRI") scanners. Our Swoop® system is designed to transform brain MR for the patient, the clinician and the provider, providing a highly differentiated experience for patients, timely imaging to clinicians, and favorable economics for hospital administrators. The Swoop® system is a portable, ULF MRI device for producing images that display the internal structures of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. Healthcare professionals can use the Swoop® system to make effective clinical diagnoses and decisions in various care settings where conventional MRI devices are inaccessible at the point of care in professional health care facilities such as emergency rooms, intensive care units, hospitals, outpatient clinics and physician offices, or rehabilitation centers. The easy-to-use interface and portable design of our Swoop® system make it easily and readily accessible anywhere in a hospital, clinic, or patient care site and it does not require any special facilities accommodations nor specialized personnel to operate safely. ULF MR does not expose patients to harmful ionizing radiation and compares favorably in this regard to X-ray computed tomography ("CT") or positron emission tomography ("PET").

The demand for MR imaging has been increasing due to the aging population and the rising prevalence of neurological, neurodegenerative, and cardiovascular conditions, recent approval of new Alzheimer's medications as well as the trends towards decentralized healthcare in mature as well as low- and middle-income countries. Healthcare professionals and insurers recognize imaging as an effective, non-invasive diagnostic tool for evaluation and ongoing monitoring. The Swoop® system is the next generation brain imaging device designed to increase access to MRI in a cost-effective manner. We believe our market opportunity is significant across the multiple sites of care where the Swoop® system brings clinical and economic value. We estimate in the United States alone our total addressable market for Swoop® system device placements to be more than \$16 billion.

Despite their advantages, many healthcare institutions worldwide lack the facilities, specialized operators, and capital necessary to acquire, maintain and staff expensive conventional MRI devices. The Swoop® system is the first U.S. Food and Drug Administration ("FDA")-cleared, portable, ULF, MR brain imaging system and is capable of providing imaging at multiple sites of care, such as intensive care units, clinics, emergency departments or physicians' offices, and can inform the timely detection, diagnosis, monitoring, and treatment of acute and chronic conditions inside and outside the hospital. We designed the Swoop® system to address the limitations of conventional imaging technologies and make MR brain imaging accessible nearly anytime and anywhere across professional healthcare settings. We believe the adoption of the Swoop® system by healthcare professionals has clinical and economic benefits throughout healthcare communities in both high and low resource settings.

The Swoop® system is AI-powered and integrates deep learning, a form of AI in the reconstruction pipeline of T1, T2, diffusion-weighted Imaging ("DWI"), and fluid-attenuated inversion recovery ("FLAIR") sequences. The integration of deep learning does not require any additional steps from the user. As a result, deep learning can enhance the image quality and, consequently, the diagnostic value of images generated at ULF. The algorithms are designed to improve ULF image quality, while reducing the impact of scan artifacts. The images created with these

algorithms were validated by expert radiologists. The Swoop® system is used clinically every day as the first mover in the field of portable ULF MRI, and with an install base that continues to expand. The learnings from this market experience have served to improve our software, AI, and denoising algorithms resulting in the image quality and performance improvements of our product over the nine software releases since our initial clearance. As we move forward, we are continuously investing in improving our AI-powered image quality and leveraging each imaging-focused software release to further improve the Swoop® system performance.

Our Swoop® system received initial 510(k) clearance for brain imaging from FDA in 2020. In February and October 2023, we received 510(k) clearances from the FDA for our Swoop® system AI-powered software. The combination of these two software updates significantly improved DWI, incorporated deep-learning based denoising in the post-processing of DWI images for crisper images, and improved image quality for all Swoop® system sequences. In July 2024, we received 510(k) clearance from the FDA of the ninth-generation AI-powered Swoop® system software. This software update significantly reduces scan times across multiple MR sequences without sacrificing image quality. Outside of the United States, the Swoop® system has received marketing authorization for brain imaging in several countries, including the European Union (CE certification), the United Kingdom (UK Conformity Assessment ("UKCA")), Canada, Australia and New Zealand. In October 2024, we received CE approval for the latest generation of software.

Key Performance Metrics

Management reviews and analyzes several key performance metrics including Total revenues and Total Swoop® system units sold. These metrics are reviewed and analyzed to evaluate our business performance, identify trends affecting our business, allocate capital, and make strategic decisions.

Total revenues were \$3.6 million and \$10.6 million for the three and nine months ended September 30, 2024, respectively, an increase of \$1.3 million, or 56.4% and \$2.2 million, or 26.6% from the three and nine months ended September 30, 2023, respectively. See "Results of Operations" below. Total Swoop® system units sold were 13 units and 39 units, for the three and nine months ended September 30, 2024, respectively, an increase of 7 units and 9 units from the three and nine months ended September 30, 2023, respectively.

Factors Affecting Results of Operations

The following factors have been important to our business and we expect them to impact our results of operations and financial condition in future periods:

Technical innovation

We have developed our Swoop® system through extensive research and development activities. Moreover, our team is dedicated to clinical support programs designed to integrate the Swoop® system into an array of diverse healthcare environments, workflow, and applications. We believe that, from our commercial and clinical experience, we are gaining invaluable insights into the Swoop® system's clinical utility. We believe these learnings will enable us to further improve our product and develop new services and tools in the future. We are continuously improving our image quality and imaging capabilities. Building upon this foundation and our expertise in ULF brain imaging, we plan to develop new imaging applications, broadening the range of clinical uses for our proprietary technology. Additionally, we are leveraging our strengths in AI and cloud technology to explore the Swoop® system's role as a brain imaging clinical decision support platform. While these technical innovations may increase our research and development expenses, we expect them to have a positive impact on our results of operations and profitability in the future.

Commercialization efforts of the Swoop® system

Our results have included revenue from the United States and outside the United States. Our Swoop® system received initial 510(k) clearance from the FDA in 2020. Initially, we have been focused on executing contracts with U.S. hospitals and hospital systems. We have built a direct sales and field support organization in the United States who are working in strong collaboration to increase adoption, support successful implementations and support

routine use at expanded customer sites. As of 2024, we have targeted a select number of international markets to add to our commercial efforts operating through distributors.

Expand sales in international markets

In 2024, we are executing on our international expansion plans by entering into agreements with experienced and accomplished distributors. We have distribution partners covering several countries across Europe and Asia Pacific, as well as Canada. With the Swoop® system's transformative, affordable, and accessible platform, we aim to serve more clinicians and patients needing brain imaging across the globe. The Swoop® system has received marketing authorization for brain imaging in several countries, including the European Union (CE certification), the United Kingdom (UKCA), Canada, Australia and New Zealand. Additionally, we have started the regulatory approval process in India through Central Drugs Standard Control Organization.

Our commitment to the vision of providing affordable and accessible imaging that enables earlier detection and timely management of health conditions worldwide is furthermore advanced by grant funding from the BMGF. Through our engagement with the BMGF, we have deployed the Swoop® system in low-middle income settings without readily-accessible MRI technology. During 2020 and 2021, we were awarded multiple grants totaling \$5.0 million from the BMGF for the provision and equipping of sites with our portable MR brain imaging system to enable the performance of a multi-site study focused on optimizing diagnostic image quality. These grants are designed to provide data to validate the use of the Swoop® system in measuring the impact of maternal anemia, malnutrition, infection and birth related injury. These grants are designed to support the deployment of a total of 25 Swoop® system devices and other services to investigators, which commenced in the spring of 2021 and was completed by February 2024. In May 2023, we were awarded an additional \$3.4 million grant from the BMGF to continue to develop a scalable approach to measuring neurodevelopment via low-field MRI in neonates, infants, and young children in low-to-middle income countries through February 2026. During the nine months ended September 30, 2024, we completed and fulfilled grant deliverables and milestones amounting to \$1.5 million and we received cash grant funding of \$1.1 million. As of September 30, 2024, we recorded restricted cash of \$0.2 million with an offset to deferred grant funding in our unaudited condensed consolidated balance sheet.

Results of Operations

The following is a discussion of our results of operations for the three and nine months ended September 30, 2024 and 2023. Our accounting policies are described under "Summary of Significant Accounting Policies" in Note 2 to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

(\$ Amounts in thousands)	Three Months Ended September 30,		Change %	Nine Months Ended September 30,		Change %
	2024	2023		2024	2023	
Sales						
Device	\$ 3,033	\$ 1,728	75.5 %	\$ 8,707	\$ 6,670	30.5 %
Service	610	602	1.3 %	1,862	1,676	11.1 %
Total sales	3,643	2,330	56.4 %	10,569	8,346	26.6 %
Cost of Sales						
Device	1,359	835	62.8 %	4,280	3,321	28.9 %
Service	376	371	1.3 %	1,224	1,302	(6.0) %
Cost of sales	1,735	1,206	43.9 %	5,504	4,623	19.1 %
Gross margin	1,908	1,124	69.8 %	5,065	3,723	36.0 %
Operating expenses:						
Research and development	5,865	5,739	2.2 %	17,394	16,531	5.2 %
General and administrative	4,510	4,615	(2.3) %	13,361	16,103	(17.0) %
Sales and marketing	2,496	2,529	(1.3) %	6,769	7,575	(10.6) %
Total operating expenses	12,871	12,883	(0.1) %	37,524	40,209	(6.7) %
Loss from operations	(10,963)	(11,759)	(6.8) %	(32,459)	(36,486)	(11.0) %
Interest income	585	1,021	(42.7) %	2,056	2,920	(29.6) %
Other income, net	52	(19)	(373.7) %	73	12	508.3 %
Loss before provision for income taxes	(10,326)	(10,757)	(4.0) %	(30,330)	(33,554)	(9.6) %
Provision for income taxes	—	—		—	—	
Net loss and comprehensive loss	\$ (10,326)	\$ (10,757)	(4.0) %	\$ (30,330)	\$ (33,554)	(9.6) %

Comparison of the Three and Nine Months Ended September 30, 2024 and 2023 (\$ Amounts shown in tables in thousands)

Sales

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change	
	2024	2023	Amount	%		2024	2023	Amount	%
Device	\$ 3,033	\$ 1,728	\$ 1,305	75.5%	\$	8,707	\$ 6,670	\$ 2,037	30.5%
Service	610	602	8	1.3%		1,862	1,676	186	11.1%
Total sales	<u>\$ 3,643</u>	<u>\$ 2,330</u>	<u>\$ 1,313</u>	56.4%	\$	<u>10,569</u>	<u>\$ 8,346</u>	<u>\$ 2,223</u>	26.6%

Device sales increased by \$1.3 million, or 75.5%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The increase in device revenue is mainly due to an increase in units sold.

Service sales in absolute dollars remained flat for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Device sales increased by \$2.0 million, or 30.5%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The increase in device revenue is mainly due to an increase in units sold.

Service sales increased by \$0.2 million, or 11.1%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This increase was driven by increased install base.

Cost of sales

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change	
	2024	2023	Amount	%		2024	2023	Amount	%
Device	\$ 1,359	\$ 835	\$ 524	62.8%	\$	4,280	\$ 3,321	\$ 959	28.9%
Service	376	371	5	1.3%		1,224	1,302	(78)	(6.0)%
Total cost of sales	<u>\$ 1,735</u>	<u>\$ 1,206</u>	<u>\$ 529</u>	43.9%	\$	<u>5,504</u>	<u>\$ 4,623</u>	<u>\$ 881</u>	19.1%
Percentage of revenue	47.6%	51.8%				52.1%	55.4%		

Cost of device sales increased by \$0.5 million, or 62.8%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This increase was driven primarily by increased units sold.

Cost of service sales in absolute dollars remained flat for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Cost of device sales increased by \$1.0 million, or 28.9%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This increase was driven primarily by increased units sold.

Cost of service sales decreased by \$0.1 million, or 6%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023.

Research and development

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change		
	2024	2023	Amount	%		2024	2023	Amount	%	
Research and development	\$ 5,865	\$ 5,739	\$ 126	2.2 %		\$ 17,394	\$ 16,531	\$ 863	5.2 %	

Research and development expenses increased by \$0.1 million, or 2.2%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This increase was driven primarily by a decrease in grant fulfillment credits of \$0.2 million partially offset by a decrease of travel expenses of \$0.1 million.

Research and development expenses increased by \$0.9 million, or 5.2%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This increase was driven primarily by an increase in personnel-related costs and stock-based compensation expenses of \$1.6 million, partially offset by \$0.7 million of a higher grant fulfillment credits.

General and administrative

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change		
	2024	2023	Amount	%		2024	2023	Amount	%	
General and administrative	\$ 4,510	\$ 4,615	\$ (105)	(2.3)%		\$ 13,361	\$ 16,103	\$ (2,742)	(17.0)%	

General and administrative expenses decreased by \$0.1 million, or 2.3%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This decrease was driven primarily by a decrease in insurance expenses of \$0.1 million.

General and administrative expenses decreased by \$2.7 million, or 17.0%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was driven primarily by a decrease in personnel-related costs and stock-based compensation expenses of \$1.5 million, a decrease in legal and patent expenses of \$0.4 million, a decrease in insurance expenses of \$0.3 million, and a decrease in subscriptions of \$0.2 million.

Sales and marketing

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change		
	2024	2023	Amount	%		2024	2023	Amount	%	
Sales and marketing	\$ 2,496	\$ 2,529	\$ (33)	(1.3)%		\$ 6,769	\$ 7,575	\$ (806)	(10.6)%	

Sales and marketing expenses in absolute dollars remained flat for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Sales and marketing expenses decreased by \$0.8 million, or 10.6%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was driven primarily by a decrease in marketing research and advertising of \$0.5 million, and a decrease in sales and marketing infrastructure of \$0.3 million, while we continue to focus on sales and sales support activities.

Interest income

	Three Months Ended September 30,		Change			Nine Months Ended September 30,		Change		
	2024	2023	Amount	%		2024	2023	Amount	%	
Interest income	\$ 585	\$ 1,021	\$ (436)	(42.7)%		\$ 2,056	\$ 2,920	\$ (864)	(29.6)%	

Interest income decreased by \$0.4 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was driven primarily by lower cash balances in money market funds and demand deposit accounts.

Interest income decreased by \$0.9 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was driven primarily by lower cash balances in money market funds and demand deposit accounts.

Other income (expense), net

	Three Months Ended September 30,				Nine Months Ended September 30,									
	2024	2023	Change		2024	2023	Change							
			Amount	%			Amount	%						
Other income (expense), net	\$	52	\$	(19)	\$	71	(373.7)%	\$	73	\$	12	\$	61	508%

Other income (expense), net increased by \$71 thousand for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. Other income, net during the three months ended September 30, 2024 was \$52 thousand consisting primarily of interest income from customer financing of approximately \$30 thousand, and a net realized gain on foreign currencies of approximately \$25 thousand, offset by other expenses of \$3 thousand.

Other income, net increased by \$61 thousand the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. Other income, net during the nine months ended September 30, 2024 was \$73 thousand consisting primarily of interest income from customer financing of approximately \$78 thousand, and a net realized gain on foreign currencies of approximately \$6 thousand, offset by other expenses of \$11 thousand.

Liquidity and Capital Resources

We have funded our operations primarily with proceeds from the issuance of common and preferred stock. We have incurred significant cash burn and recurring net losses, which includes a net loss of \$30.3 million for the nine months ended September 30, 2024, and an accumulated deficit of \$284.0 million as of September 30, 2024. As of September 30, 2024, we had cash and cash equivalents of \$45.8 million. As we continue to invest in research and development of our products and sales and marketing, we expect to continue to incur a significant cash burn and recurring net losses for the foreseeable future until such time that our product and services sales generate enough gross profit to cover our operating expenses. However, we can provide no assurance that our product and service sales will generate a net profit in the future or that our cash resources will be sufficient to continue our commercialization and development activities.

In November 2023, we filed a shelf registration statement on Form S-3 with the SEC pursuant to which we registered for sale up to \$150 million of any combination of our Class A common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. Our shelf registration statement on Form S-3 also includes a prospectus (the "Sales Agreement Prospectus") covering up to an aggregate of \$50.0 million in shares of Class A common stock that we may issue and sell from time to time, through B. Riley Securities, Inc. ("B. Riley") acting as our sales agent, pursuant to the sales agreement that we entered into with B. Riley in November 2023 (the "Sales Agreement"), for our "at-the-market" equity program. We are not obligated to make any sales of Class A common stock under the Sales Agreement. As of the filing of our 2023 Annual Report on Form 10-K, we are subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by non-affiliates. Therefore, we are limited in the amount of proceeds we are able to raise by selling shares of our common stock using our Form S-3, including under the Sales Agreement, until such time as our public float exceeds \$75 million. On March 22, 2024, we filed an amendment to the Sales Agreement Prospectus, pursuant to which, as of such date, we may offer and sell shares of our Class A common stock having an aggregate offering price of up to \$22.8 million from time to time through or to B. Riley. As of September 30, 2024 and during the three months ended September 30, 2024, a total of 728,188

shares of our Class A common stock, for total gross and net proceeds of \$0.8 million, have been issued and sold under the Sales Agreement.

Our ability to access capital when needed is not assured and, if capital is not available when, and in the amounts needed, we could be required to delay, scale back or abandon some or all of our development programs, commercialization of our products, and other operations which could materially harm our operations, financial condition and operating results. We expect that our existing cash and cash equivalents, together with proceeds from the sales of our products and services, will enable us to conduct our planned operations for at least the next 12 months. Factors that could accelerate cash needs include: (i) delays in achieving scientific and technical milestones; (ii) unforeseen capital expenditures and fabrication costs related to manufacturing; (iii) changes we may make in our business or commercialization and hiring strategy; (iv) costs of running a public company; (v) higher inflation and increases in product transportation and labor costs; and (vi) other items affecting our forecasted level of expenditures and use of cash resources including potential acquisitions.

We expect to use our cash to further invest in the development of our products and services, commercial expansion, and for working capital and general corporate purposes.

Our future cash requirements will depend on many factors, including market adoption of our products; the cost and timing of establishing additional sales, marketing and distribution capabilities; the cost of our research and development activities; our ability to enter into and maintain collaborations; the cost and timing of potential future regulatory clearances or approvals for our products; and the effect of competing technological and market developments. We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have or are not able to obtain sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products and services or cease operations.

Cash

As of September 30, 2024, we had cash and cash equivalents of \$45.8 million. Our future capital requirements may vary from those currently planned and will depend on various factors including further development costs, commercialization strategy, international expansion, and regulatory costs. If we need additional funds and are unable to obtain funding on a timely basis, we may need to curtail significantly our product development and commercialization efforts to provide sufficient funds to continue our operations, which could adversely affect our business prospects.

Cash flows

The following table summarizes our cash flows for the periods indicated:

(In thousands)	Nine Months Ended September 30,			
	2024		2023	
Net cash used in operating activities	\$	(30,410)	\$	(31,871)
Net cash used in investing activities		(375)		(546)
Net cash provided by financing activities		965		146
Net decrease in cash, cash equivalents, and restricted cash	\$	(29,820)	\$	(32,271)

Net cash used in operating activities

For the nine months ended September 30, 2024, net cash used in operating activities of \$30.4 million was due primarily to a net loss of \$30.3 million and changes in operating assets and liabilities of \$4.3 million, partially offset

by non-cash items of \$4.2 million. Non-cash items were primarily stock-based compensation expense of \$3.3 million, depreciation expense of \$0.8 million and loss on disposal of property and equipment, net of \$0.2 million. Changes in operating assets and liabilities were driven primarily by an increase in accounts receivable and unbilled receivables of \$4.9 million driven primarily by increased revenue, an increase in inventory of \$0.6 million, and an increase in prepaid expenses and other current assets of \$0.3 million, partially offset by an increase in accrued expense and other current liabilities of \$0.9 million and a decrease in prepaid inventory of \$0.7 million.

For the nine months ended September 30, 2023, net cash used in operating activities of \$31.9 million was due primarily to a net loss of \$33.6 million and changes in operating assets and liabilities of \$2.6 million, partially offset by non-cash items of \$4.4 million. Non-cash items were primarily stock-based compensation expense of \$3.5 million and depreciation expense of \$0.8 million. Changes in operating assets and liabilities were driven primarily by an increase in inventory of \$2.5 million, a decrease in accrued expenses and other liabilities of \$0.8 million, a decrease in deferred revenue of \$0.4 million, an increase in accounts receivable of \$0.3 million, and an increase in unbilled receivables of \$0.2 million, partially offset by a decrease in prepaid expenses and other current assets of \$1.0 million, a decrease in prepaid inventory of \$0.3 million, and an increase in accounts payable of \$0.2 million.

Net cash used in investing activities

For the nine months ended September 30, 2024, net cash used in investing activities of \$0.4 million was from fixed assets purchased.

For the nine months ended September 30, 2023, net cash used in investing activities of \$0.5 million was from fixed assets purchased.

Net cash provided by financing activities

For the nine months ended September 30, 2024, net cash provided by financing activities of \$1.0 million consisting primarily of proceeds from issuance of Class A common stock under the Sales Agreement of \$0.8 million and proceeds from stock options exercises of \$0.2 million.

For the nine months ended September 30, 2023, net cash provided by financing activities of \$0.1 million was proceeds from option exercises.

Contractual obligations

We sponsor a 401(k) defined contribution plan covering all eligible U.S. employees. Contributions to the 401(k) plan are discretionary. We did not make any matching contributions to the 401(k) plan for the three and nine months ended September 30, 2024 and 2023.

Through our engagement with the BMGF, we have deployed and continue to deploy the Swoop® system in low-middle income settings without readily-accessible MRI technology. The multiple grants provided by our research partnership with the BMGF, which commenced funding in the spring of 2020, support the deployment of 25 Swoop® system and accessories to investigators. The ongoing investigation is designed to provide data to validate the potential use of the Swoop® system in measuring the impact of maternal anemia, malnutrition, infection, and birth-related injury. In May 2023, we were awarded an additional 3-year grant from the BMGF to continue to develop a scalable approach to measuring neurodevelopment via ULf brain imaging in neonates, infants, and young children in low-to-middle income countries.

Our purchase commitments and obligations include all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services.

We had no other significant contractual obligations as of September 30, 2024.

For information on contingencies, refer to Note 13 in the notes to our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2024 and 2023 included elsewhere in this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Significant Judgments 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 ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. 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 items that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Except as described in Note 2 "Summary of Significant Accounting Policies – Recently Issued Accounting Pronouncements", to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in our 2023 Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements and notes thereto for the three and nine months ended September 30, 2024 and 2023 included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of business. Market risk represents the risk of loss that may impact our results of operations or financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates, inflation risk, and foreign exchange risk. We do not hold, issue or enter into any financial instruments for speculative or trading purposes. We do not have significant exposure to foreign currencies.

Interest Rate Risk

Our cash, cash equivalents and restricted cash as of September 30, 2024 consisted of \$46.0 million in money market funds, demand deposit and savings accounts. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash equivalents. Based on our balance sheet position at September 30, 2024, the annualized effect of a 0.5 percentage point decrease in interest rates would be to decrease earnings before income taxes by \$0.2 million.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations, other than its impact on the general economy. Nonetheless, if our costs were to become subject to inflationary pressures, we might not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Foreign Exchange Risk

We operate our business primarily within the United States and currently execute the majority of our transactions in U.S. dollars. We have not utilized hedging strategies with respect to such foreign exchange exposure. This limited foreign currency translation risk is not expected to have a material impact on our condensed consolidated financial statements.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2024. Based upon that evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2024, the end of the period covered by this report, our disclosure controls and procedures were effective at a reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Our business, results of operations and financial condition are subject to various risks and uncertainties including the risk factors described under the caption "Risk Factors" in our 2023 Annual Report on Form 10-K and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. There have been no material changes in our risk factors from those described in our 2023 Annual Report on Form 10-K or our Quarterly Report on Form 10-Q referenced above. We may disclose changes to risk factors or additional risk factors from time to time in our future filings with the SEC.

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

Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three and nine months ended September 30, 2024, none of our officers or directors adopted, modified or terminated any such trading arrangements.

Item 6. Exhibits

See Exhibit Index.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
31.1	<u>Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
31.2	<u>Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
32*	<u>Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	X			
101.INS	Inline XBRL Instance Document - The instance document does not appear in the Interactive Data File because its Inline XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).	X			

* The certifications attached as Exhibit 32 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Hyperfine, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Date: November 12, 2024

HYPERFINE, INC.

By: /s/ Maria Sainz

Maria Sainz

President and Chief Executive Officer

Date: November 12, 2024

By: /s/ Brett Hale

Brett Hale

Chief Administrative Officer, Chief Financial Officer, Treasurer and
Corporate Secretary

CERTIFICATIONS UNDER SECTION 302

I, Maria Sainz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Hyperfine, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - 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, 2024

/s/ Maria Sainz

Maria Sainz

President and Chief Executive Officer
(principal executive officer)

CERTIFICATIONS UNDER SECTION 302

I, Brett Hale, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Hyperfine, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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, 2024

/s/ Brett Hale

Brett Hale

Chief Administrative Officer, Chief Financial Officer, Treasurer and
Corporate Secretary
(principal financial officer)

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Hyperfine, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended September 30, 2024 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2024

/s/ Maria Sainz
Maria Sainz
President and Chief Executive Officer
(principal executive officer)

Dated: November 12, 2024

/s/ Brett Hale
Brett Hale
Chief Administrative Officer, Chief Financial Officer,
Treasurer and Corporate Secretary
(principal financial officer)
