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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 09, 2026

Hyperfine, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39949**	**98-1569027**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
351 New Whitfield Street Guilford, Connecticut		**06437**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (866) 796-6767

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2026, Hyperfine, Inc. issued a press release announcing its results for the third quarter ended September 30, 2026 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated November 9, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

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 hereunto duly authorized.

HYPERFINE, INC.

Date: November 9, 2026

By: /s/ Brett Hale

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

Exhibit 99.1

Hyperfine, Inc. Reports Third Quarter 2026 Financial Results

GUILFORD, Conn.--(BUSINESS WIRE)--November 9, 2026--Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable MRI system for the brain—the Swoop® system—today announced third quarter 2026 financial results and provided a business update.

“Q3 2026 marked the beginning of a new trajectory for Hyperfine. We delivered record revenue, gross profit, and gross margin, and for the first time quarterly revenue exceeded net cash burn, demonstrating the operating leverage of our business. The combination of AI with accessible brain imaging enables diagnostic insights at scale, sooner, and in more care settings, from the health system to the community. Beyond our current business, I am excited about the opportunities for our Swoop® system in the evolving brain health and longevity fields. This is the new Hyperfine,” said Maria Sainz, President and Chief Executive Officer of Hyperfine, Inc.

Recent Achievements and Business Highlights

- Completed enrollment in the Contrast PMR study, a key milestone toward expanding the Swoop® system's labeling, with FDA submission remaining on track and expected by the end of 2026.
- Launched Swoop® system Model 2 in Europe and the UK following CE and UKCA marking, with sales into four international markets, and signed an exclusive distributor agreement for Kuwait and the United Arab Emirates.
- Received FDA clearance and CE and UKCA marking for the latest Optive AI™ software. The software release improves noise correction, adds guided scanning, and introduces an isotropic T1 sequence.
- Published NEURO PMR study results in the *Journal of Neuroimaging*, showing 92% concordance between portable MRI and high-field MRI in blinded review, and 98% concordance when paired with clinical information.
- Expanded Swoop® system evidence base with new peer-reviewed *Stroke* and *Journal of Neurosurgery* publications, adding to more than 180 publications and 280 scientific presentations to date.

Third Quarter 2026 Financial Results

- Revenues for the third quarter of 2026 were a record $6.0 million, increasing 73% compared to $3.4 million in the third quarter of 2025 and 53% compared to $3.9 million in the second quarter of 2026.
- Sold 14 commercial Swoop® systems in the third quarter of 2026, increasing 75% compared to 8 sold in the third quarter of 2025.
- Gross profit for the third quarter of 2026 was a record $3.4 million, compared to $1.8 million in the third quarter of 2025, representing a record 57% gross margin in the third quarter of 2026, compared to 54% gross margin in the third quarter of 2025.
- Research and development expenses for the third quarter of 2026 were $3.9 million, decreasing 3% compared to $4.0 million in the third quarter of 2025.
- Sales, marketing, general, and administrative expenses for the third quarter of 2026 were $6.7 million, relatively flat compared to $6.7 million in the third quarter of 2025.
- Operating loss for the third quarter of 2026 was $7.3 million, the Company's narrowest quarterly operating loss, an improvement of 19% compared to $8.9 million in the third quarter of 2025. Revenue grew 73% and gross profit grew 83% while total operating expenses decreased 1%, reflecting the operating leverage of the business.
- Net loss for the third quarter of 2026 was $6.0 million, equating to a net loss of $0.06 per share, as compared to a net loss of $11.0 million, or a net loss of $0.14 per share, for the third quarter of 2025. The third quarter of 2026 net loss includes a $1.5 million gain from a change in the fair value of warrant liabilities, compared to a $2.3 million loss in the third quarter of 2025.
- Net cash burn[1] for the third quarter of 2026 was $5.6 million, the Company's lowest quarterly net cash burn, compared to $5.9 million in the third quarter of 2025 and $7.9 million in the second quarter of 2026. Third quarter 2026 revenue exceeded net cash burn for the first time.
- Cash and cash equivalents were $37.9 million as of September 30, 2026. The Company did not generate any financing proceeds during the third quarter of 2026.

2026 Financial Guidance

- Management continues to expect revenue for the full year 2026 to be approximately $20 to $22 million, representing 55% growth at the midpoint as compared to full year 2025.
- Management continues to expect net cash burn[1] for the full year 2026 to be approximately $26 to $28 million, representing a 10% decline at the midpoint as compared to full year 2025.

[1]Net cash burn is calculated as change in cash and cash equivalents less net financing proceeds, including net proceeds from shares issued under the Company's "at-the-market" offering program, the Company's February 2025 registered direct offering, the Company's October 2025 underwritten public offering, warrant exercises, and the Company's March 2026 debt financing. Cash and cash equivalents were $40.8 million as of March 31, 2026, $43.5 million as of June 30, 2026 and $37.9 million as of September 30, 2026; net financing proceeds in the aggregate were $10.6 million for the quarter ended June 30, 2026 and $0.0 million for the quarter ended September 30, 2026. Cash and cash equivalents were $25.4 million as of June 30, 2025; net financing proceeds in the aggregate were $2.1 million for the quarter ended September 30, 2025. Cash and cash equivalents were $37.6 million as of December 31, 2024, $21.6 million as of September 30, 2025, $35.1 million as of December 31, 2025, and $37.9 million as of September 30, 2026; net financing proceeds in the aggregate were $8.1 million for the nine months ended September 30, 2025 and $25.0 million for the nine months ended September 30, 2026. Net financing proceeds in the aggregate were $27.3 million for the year ended December 31, 2025. All quarterly numbers presented herein are unaudited. The Company has not provided a reconciliation of full year 2026 net cash burn guidance to forward-looking net change in cash and cash equivalents, because the amount and timing of future financing proceeds cannot be predicted without unreasonable efforts.

Corporate Update

The Company expects to file a new registration statement on Form S-3 to replace its existing shelf registration statement, which is scheduled to expire in November 2026. The new universal shelf registration statement is expected to register an aggregate offering amount of $150 million, including a $50 million "at-the-market" offering program prospectus supplement, which is consistent with the existing registration statement.

Conference Call

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/ 4:30 p.m. ET on Monday, November 9, 2026 to discuss its third quarter 2026 financial results and provide a business update. Those interested in listening should register online by visiting https://investors.hyperfine.io/ and clicking on News & Events. Participants are encouraged to register more than 15 minutes before the start of the call. A live and archived audio webcast will be available through the Investors page of Hyperfine, Inc.'s corporate website at https://investors.hyperfine.io/.

About Swoop® Portable MR Imaging® Systems

The Swoop® Portable MR Imaging® systems are U.S. Food and Drug Administration (FDA)-cleared for brain imaging of patients of all ages. They are portable, ultra-low-field magnetic resonance imaging devices for producing images that display the internal structure 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. The Swoop® system also has CE Mark in the European Union and UKCA Mark in the United Kingdom. The Swoop® system is commercially available in a select number of international markets.

About Hyperfine, Inc.

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of professional care. The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the Swoop® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. For more information, visit hyperfine.io.

The Hyperfine logo, Swoop, and Portable MR Imaging are registered trademarks of Hyperfine, Inc. The Swoop logo, Optive AI logo, and Optive AI are trademarks of Hyperfine, Inc.

Use of Non-GAAP Financial Information

Hyperfine, Inc. has presented certain financial information in accordance with U.S. GAAP and on a non-GAAP basis. The non-GAAP financial measure included in this press release is net cash burn. Management uses this non-GAAP financial measure, in addition to GAAP financial measures, as a measure of operating performance because the non-GAAP financial measure does not include the impact

of items that management does not consider indicative of Hyperfine, Inc.'s core operating performance. Management believes that this non-GAAP financial measure, taken in conjunction with GAAP financial measures, provides useful information for both management and investors by excluding certain financing proceeds that are not indicative of the Company's core operating results. Management uses non-GAAP measures to compare the Company's performance relative to forecasts and strategic plans and to benchmark the Company's performance externally against competitors. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of the Company's operating results as reported under U.S. GAAP. Hyperfine, Inc. encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. The reconciliation between the most directly comparable GAAP measure, net change in cash and cash equivalents, and historical non-GAAP net cash burn is presented in footnote 1 above. A reconciliation of the Company's full-year 2026 net cash burn guidance to the most directly comparable GAAP measure is not provided because the Company is unable to predict certain components of such measure, including future financing proceeds, without unreasonable efforts. Future financing proceeds could cause the Company's actual net change in cash and cash equivalents to differ materially from its net cash burn guidance.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the "Company") may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, expectations about the Company's financial and operating results, including the Company's expected revenue and net cash burn for the full year 2026, the Company's goals and commercial plans, the acceleration of the adoption of the Swoop® system across multiple sites of care in the hospital, office-based, wellness and longevity, and mobile settings, and international markets, the benefits of the Company's products and services, progress on improvements and advancements in the Company's products and services, and the Company's future performance, including its financial performance, and its ability to implement its strategy, including its entrance into new markets. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of the Company's product development and commercialization activities, including the degree that the Swoop® system is accepted and used by healthcare professionals; the Company's ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the ability of the Company to raise financing in the future; the ability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the ability of the Company to identify, in-license or acquire additional technology; the ability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; existing and potential future National Institutes of Health funding pressures; existing and potential future effects from U.S. export controls and tariffs; the ability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently marketing or developing; the size and growth potential of the markets for the Company's products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company's products and services and reimbursement for medical procedures conducted using the Company's products and services; the Company's ability to successfully complete and generate positive data from the PRIME study and Contrast PMR study; the Company's ability to generate clinical evidence of the benefits of the Company's products and services and to progress on product advancements and improvements; the Company's estimates regarding expenses, revenue, capital requirements and needs for additional financing; the Company's financial performance; the inability to maintain the listing of the Company's Class A common stock on the Nasdaq Stock Market; and other risks and uncertainties indicated from time to time in the Company's filings with the Securities and Exchange Commission, including those under "Risk Factors" therein. The Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

Investor Contact
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HYPERFINE

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

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 37,872	$ 35,085
Restricted cash	778	957
Accounts receivable, less allowance of $539 and $1,372 as of September 30, 2026 and December 31, 2025, respectively	5,180	5,254
Unbilled receivables	1,314	1,268
Inventories	6,378	7,090
Prepaid expenses and other current assets	2,228	1,255
Total current assets	53,750	50,909
Property and equipment, net	2,094	2,549
Other long-term assets	1,949	1,804
Total assets	**$ 57,793**	**$ 55,262**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,692	$ 4,051
Deferred grant funding	778	957
Deferred revenue	1,737	1,544
Due to related parties	8	50
Accrued expenses and other current liabilities	6,317	5,130
Total current liabilities	10,532	11,732
Long-term debt, net	13,352	—
Warrant liabilities	1,026	1,730
Long term deferred revenue	830	729
Other noncurrent liabilities	309	66
Total liabilities	**26,049**	**14,257**
STOCKHOLDERS' EQUITY		
Class A Common stock, $0.0001 par value per share; 600,000,000 shares authorized; 91,143,884 and 82,166,458 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	9	8
Class B Common stock, $0.0001 par value per share; 27,000,000 shares authorized; 15,055,288 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	2	2
Additional paid-in capital	385,651	371,011
Accumulated deficit	(353,918)	(330,016)
Total stockholders' equity	**31,744**	**41,005**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 57,793**	**$ 55,262**

HYPERFINE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Sales				
Device	$ 5,243	$ 2,891	$ 11,670	$ 6,541
Service	717	546	2,097	1,729
Total sales	$ 5,960	$ 3,437	$ 13,767	$ 8,270
Cost of sales				
Device	$ 2,290	$ 1,328	$ 5,539	$ 3,410
Service	288	261	887	801
Total cost of sales	$ 2,578	$ 1,589	$ 6,426	$ 4,211
Gross profit	**3,382**	**1,848**	**7,341**	**4,059**
Operating Expenses:				
Research and development	$ 3,913	$ 4,048	$ 11,623	$ 13,626
General and administrative	4,051	4,152	12,088	12,219
Sales and marketing	2,675	2,568	7,914	7,631
Total operating expenses	**$ 10,639**	**$ 10,768**	**$ 31,625**	**$ 33,476**
Loss from operations	**$ (7,257)**	**$ (8,920)**	**$ (24,284)**	**$ (29,417)**
Interest income	291	187	817	743
Interest expense	(549)	—	(1,165)	—
Change in fair value of warrant liabilities	1,516	(2,303)	704	(639)
Other income (expense), net	18	17	26	(349)
Loss before provision for income taxes	**$ (5,981)**	**$ (11,019)**	**$ (23,902)**	**$ (29,662)**
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	**$ (5,981)**	**$ (11,019)**	**$ (23,902)**	**$ (29,662)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.06)	$ (0.14)	$ (0.24)	$ (0.38)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	106,110,069	79,028,987	101,231,610	77,613,306

HYPERFINE

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

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (23,902)	$ (29,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	789	809
Stock-based compensation expense	2,512	2,109
Loss on disposal of property and equipment, net	6	120
Change in fair value of warrant liabilities	(704)	639
Amortization of debt discount and issuance costs	246	—
Other	21	22
Changes in assets and liabilities:		
Accounts receivable, net	74	1,070
Unbilled receivables	(46)	926
Inventory	685	(221)
Prepaid expenses and other current assets	(998)	(802)
Other long term assets	274	51
Accounts payable	(2,400)	2,112
Deferred grant funding	(179)	438
Deferred revenue	294	(105)
Due to related parties	(42)	(16)
Accrued expenses and other current liabilities	1,008	(221)
Operating lease liabilities, net	3	(10)
Net cash used in operating activities	**$ (22,359)**	**$ (22,741)**
Cash flows from investing activities:		
Purchases of property and equipment	(293)	(1,122)
Net cash used in investing activities	**$ (293)**	**$ (1,122)**
Cash flows from financing activities:		
Proceeds from issuance of debt, net	$ 13,626	$ —
Proceeds from exercise of stock options	259	130
Proceeds from issuance of Class A common stock under “at-the-market” offering program, net	11,375	2,906
Proceeds from issuance of Class A common stock with warrants under February 2025 Offering, net	—	5,184
Net cash provided by financing activities	**$ 25,260**	**$ 8,220**
Net increase (decrease) in cash and cash equivalents and restricted cash	2,608	(15,643)
Cash, cash equivalents and restricted cash, beginning of period	36,042	37,673
Cash, cash equivalents and restricted cash, end of period	**$ 38,650**	**$ 22,030**
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	$ 37,872	$ 21,564
Restricted cash	778	466
Total cash, cash equivalents and restricted cash	**$ 38,650**	**$ 22,030**
Supplemental disclosure of noncash information:		
Issuance of warrants in connection with Loan Agreement, net	**$ 495**	**$ —**
Initial measurement of warrant liabilities	**$ —**	**$ 2,858**
Unpaid purchase of property and equipment	**$ 72**	**$ 5**
Noncash acquisition of fixed assets	**$ 27**	**$ —**
Right-of-use assets obtained in exchange for new operating lease liabilities	**$ 735**	**$ —**