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): February 16, 2023

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 8.01. Other Events.

As previously reported, on December 6, 2022, Hyperfine, Inc. (the "Company") received written notice (the "Notice") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, because the closing bid price for the Company's Class A common stock, par value $0.0001 per share (the "Common Stock"), had fallen below $1.00 per share for 30 consecutive business days, the Company was not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement").

On February 16, 2023, the Company received a letter from the Staff of Nasdaq indicating that it has regained compliance with the Bid Price Requirement and this matter is now closed.

In addition, on February 21, 2023, the Company issued a press release announcing that it received CE marking of its Swoop® Portable MR Imaging®System in the European Union. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated February 21, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 21, 2023

By: /s/ Maria Sainz
Maria Sainz

President and Chief Executive Officer

Hyperfine, Inc. Swoop® Portable MR Imaging® System Receives CE Marking After Meeting Comprehensive New EU MDR Regulations

CE Marking for the company's portable MRI system with AI-powered imaging software demonstrates that the system complies with safety and performance requirements in the EU and provides the company optionality for future expansion beyond the current commercial focus

GUILFORD, CT – February 21, 2023 — Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that created the Swoop® system, the world's first FDA-cleared portable MRI system, today announced CE Marking for the product. While the company will maintain its commercial focus in the U.S. in 2023, CE Marking opens the door for potential future commercial expansion into the European Economic Area (EEA).

To receive CE Marking, medical device companies must comply with the European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR). EU MDR dictates the European distribution of medical devices, and compliance is mandatory to legally market and sell products in the EEA. Recent MDR mandates have raised the bar for manufacturers, requiring them to meet more stringent guidelines, and placing increased importance on a Clinical Evaluation Report (CER), a detailed analysis of clinical data about a medical device to support safety and performance.

"Receiving CE marking for our portable MRI system with AI-powered imaging software is a significant achievement for our company and enables opportunities for future geographic expansion beyond our current commercial focus in the United States," stated Maria Sainz, president and CEO of Hyperfine, Inc. "The standard for bringing medical devices to market in the EU has become significantly more stringent under the new MDR regulations, and we are proud to have accomplished compliance with these demanding standards."

For more information about the Swoop® Portable MR Imaging® System, please visit http://www.hyperfine.io.

About Hyperfine, Inc. and the Swoop® Portable MR Imaging® System
Hyperfine, Inc. (NASDAQ: HYPR) is the groundbreaking medical technology company that created the Swoop® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) system capable of providing neuroimaging at the point of care. The Swoop® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a bedside magnetic resonance imaging device 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 has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, CE certification in the European Union, and is also available in New Zealand and Pakistan.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging, and data solutions. 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. Traditionally, access to costly,

stationary, conventional MRI technology can be inconvenient or not available when needed most. With the portable, ultra-low-field Swoop® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit hyperfine.io.

Hyperfine, Swoop, and Portable MR Imaging are registered trademarks of Hyperfine, Inc.

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. Hyperfine, Inc. ("the Company")'s actual results 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 commercial plans, the benefits of the Company's products and services, and the Company's future performance and its ability to implement its strategy. 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 impact of COVID-19 on the Company's business; the inability to maintain the listing of the Company's Class A common stock on the Nasdaq; the inability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition and the Company's ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability 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 inability of the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability 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 estimates regarding expenses, future revenue, capital requirements and needs for additional financing; Company's financial performance; and other risks and uncertainties indicated from time to time in Company's filings with the Securities and Exchange Commission, including those under "Risk Factors" therein. 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.

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Media Contact

Annika Parrish
Health+Commerce
annika@healthandcommerce.com

Investor Contact
Marissa Bych
Gilmartin Group LLC
marissa@gilmartinir.com