

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): **January 10, 2022**

HYPERFINE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

351 New Whitfield Street
Guilford, Connecticut
(Address of principal executive offices)

001-39949
(Commission File Number)

98-1569027
(IRS Employer
Identification No.)

06437
(Zip Code)

Registrant's telephone number, including area code: **(203) 458-7100**

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, par value \$0.0001 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 January 10, 2022, Hyperfine, Inc. (“Hyperfine”) issued a press release reporting preliminary unaudited financial information, including preliminary unaudited total revenue, for the quarter ended December 31, 2021 and the year ended December 31, 2021, and other information about Hyperfine’s business.

In addition, from time to time, Hyperfine presents and/or distributes slides and presentations to the investment community to provide updates and summaries of its business. On January 10, 2022, Hyperfine updated its corporate presentation, which is available on the “Investors” section of Hyperfine’s website at <https://hyperfine.io/>. The corporate presentation includes preliminary unaudited financial information, including preliminary unaudited total revenue, for the quarter ended December 31, 2021 and the year ended December 31, 2021, and other information about Hyperfine’s business.

Item 7.01 Regulation FD Disclosure.

The press release issued on January 10, 2022 and the corporate presentation updated on January 10, 2022 also include information about Hyperfine’s business and operations. This press release and corporate presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and Exhibit 99.2) 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 No.	Description
99.1	Press Release issued by Hyperfine, Inc. on January 10, 2022
99.2	Corporate Presentation of Hyperfine, Inc. dated January 10, 2022
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.

By: /s/ Dave Scott
Name: Dave Scott
Title: Chief Executive Officer

Date: January 10, 2022



Hyperfine Reports Preliminary Unaudited 2021 Revenue and Swoop® System Installations

GUILFORD, Connecticut, January 10, 2022 (GLOBE NEWSWIRE) – Hyperfine (Nasdaq: HYPR), the groundbreaking medical device company that created Swoop®, the world's first FDA-cleared portable MRI system™, today announced preliminary unaudited revenue for the fourth quarter and full year ended December 31, 2021.

Preliminary unaudited total revenue for the fourth quarter 2021 is expected to be approximately \$0.362 to \$0.437 million. Preliminary unaudited total revenue for the full year 2021 is expected to be approximately \$1.42 to \$1.50 million. Additionally, the company realized a total of \$0.81 million in grant funding for the fourth quarter of 2021 and a total of \$1.45 million in grant funding for the full year 2021 as part of grant fulfillment for Swoop installations.

The Swoop total installed base consists of three components, discussed in further detail below: Commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations. The Swoop total installed base (or total installed units) is the number of Swoop devices deployed to hospitals, other healthcare providers, and research institutions. Hyperfine views the total installed base as a key metric of the growth of its business and is measured from period over period. Presented below is a breakout of total Swoop systems installed during 2020 and 2021:

TOTAL INSTALLED UNITS

	2020	2021				TOTAL
		Q1	Q2	Q3	Q4	
Commercial Systems Installations	4	5	7	4	7	27
Grant Fulfillment Installations	0	2	2	4	10	18
	4	7	9	8	17	45
Research Units	15	2	2	3	3	25
Total Installed Units	19	9	11	11	20	70

- Commercial system installations reflect device sales and subscription services through commercial agreements (commercial sales) or through research transfer agreements (RTA sales). Commercial sales are made to hospitals and other healthcare providers as direct sales of devices and software subscription services or through subscriptions for the use of the device and software. RTA sales represent the sale of Swoop units for research use purposes. Hyperfine's revenue for the years ended December 31, 2021, and 2020 is derived from commercial sales and RTA sales.
- Grant fulfillment installations consist of shipments of Swoop units to hospitals and other clinical facilities designated by the Bill & Melinda Gates Foundation (BMGF). The corresponding funding for these installations from BMGF is recorded as a reduction in the research and development expenses when realized during the period.
- Research units represent installed units, at no cost to the institutions, to expand clinical use cases. The installation of research units is recorded as a fixed asset with the related depreciation recorded as R&D expense over the life of the research unit.



“2021 was a transformational year for Hyperfine and a year of significant achievements in driving our clinical and value proposition forward while establishing strong early commercial traction,” said Dave Scott, president and chief executive officer. “We are pleased to have installed over 50 Swoop devices in 2021, our first full year of commercialization, against the challenges posed by a global pandemic. We see a substantial opportunity and strong growth trajectory ahead as we expand our sales force, build relationships with new partners and medical centers, and invest substantially in further applications of low-field, portable MRI to increase our impact for patients in need of medical imaging around the world. This is just the first step in our journey to democratize imaging, sensing, and ultimately guided intervention, and I am incredibly optimistic about our future.”

About Hyperfine

Hyperfine, Inc. is the groundbreaking medical device company that created Swoop®, the world’s first FDA-cleared portable MRI system. Hyperfine designed Swoop to enable rapid diagnoses and treatment for every patient regardless of income, resources, or location, pushing the boundaries of conventional imaging technology and expanding patient access to life-saving care. The Swoop Portable MR Imaging System™ produces high-quality images at a lower magnetic field strength, allowing clinicians to quickly scan, diagnose, and treat patients in various clinical settings. Swoop can be wheeled directly to the patient’s bedside, plugged into a standard electrical wall outlet, and controlled by an iPad®. Designed as a complementary system to conventional MRIs at a fraction of the cost, Swoop captures images in minutes, providing critical decision-making capabilities in emergency departments, operating rooms outside the sterile field, and intensive care units, among others.

Preliminary Financial Information

The preliminary financial information included in this press release is unaudited and is subject to completion of Hyperfine’s quarter and year-end closing procedures and further financial review. In certain cases, Hyperfine has provided expected ranges, rather than specific amounts, because these results are preliminary and subject to change. Actual results may differ from these estimates as a result of the completion of our quarter and year-end closing procedures, review adjustments and other developments that may arise between now and the time such financial information for the period is finalized. As a result, these estimates are preliminary, may change and constitute forward-looking information and, as a result, are subject to risks and uncertainties. These preliminary estimates should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles (GAAP), and they should not be viewed as indicative of our results for any future period. Hyperfine’s independent registered public accountants have not audited, reviewed, compiled, or performed any procedures with respect to these estimated financial results and, accordingly, do not express an opinion or any other form of assurance with respect to these preliminary estimates.



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’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 Hyperfine’s financial and operating results, the benefits of Hyperfine’s products and services, and Hyperfine’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 Hyperfine’s control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the completion and audit of Hyperfine’s financial statements for the year ended December 31, 2021; the success, cost and timing of Hyperfine product development and commercialization activities, including the degree that Swoop is accepted and used by healthcare professionals; the impact of COVID-19 on Hyperfine’s business; the inability to maintain the listing of Hyperfine’s Class A common stock on the Nasdaq following the recently completed business combination; the inability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition and Hyperfine’s ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of Hyperfine to raise financing in the future; the inability of Hyperfine 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 Hyperfine to identify, in-license or acquire additional technology; the inability of Hyperfine to maintain its existing or future license, manufacturing, supply and distribution agreements; the inability of Hyperfine to compete with other companies currently marketing or engaged in the development of products and services that Hyperfine is currently marketing or developing; the size and growth potential of the markets for Hyperfine’s products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of Hyperfine’s products and services and reimbursement for medical procedures conducted using Hyperfine’s products and services; Hyperfine’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; Hyperfine’s financial performance; and other risks and uncertainties indicated from time to time in Hyperfine’s filings with the Securities and Exchange Commission, including those under “Risk Factors” therein. Hyperfine 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. Hyperfine 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.

Hyperfine Contact

Emily Barnes
APCO Worldwide
ebarnes@apcoworldwide.com

Investor Contact

Marissa Bych
Gilmartin Group LLC
investors@hyperfine.io

HYPERFINE

Defining the Future of Life-Saving Diagnostics at the Point of Care

Corporate Presentation | January 2022

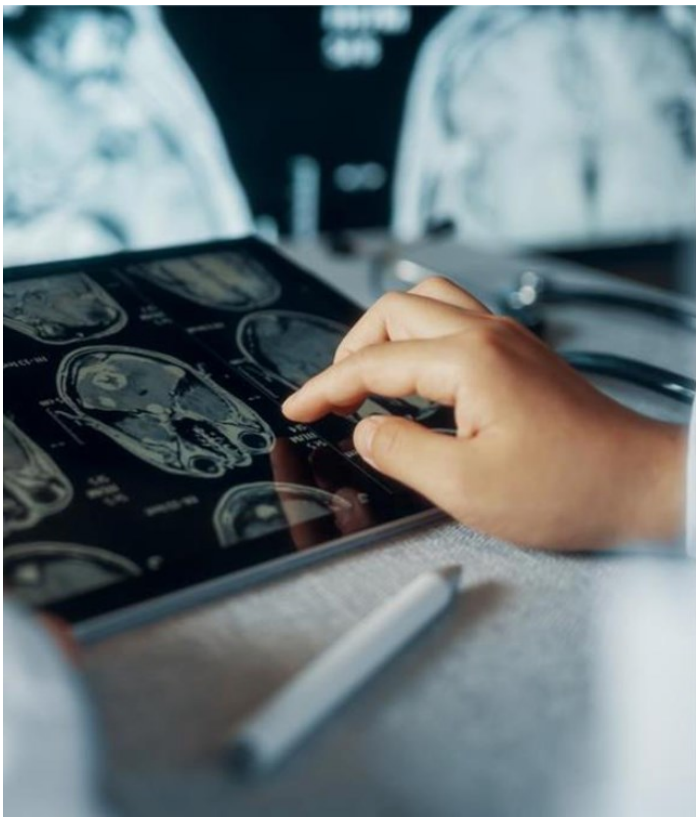
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Today, brain diagnostics are single point-in-time and delay the time from door to discharge.



Our mission is to transform patient care by creating access to life-saving diagnostics and actionable data at the point-of-care.

HYPERFINE

The Hyperfine Ecosystem

Democratizing **Imaging**, **Sensing**, and **Guided Intervention** to cover the care continuum

Imaging
(FDA cleared)



Sensing
(in development)



Intervention
(in development)



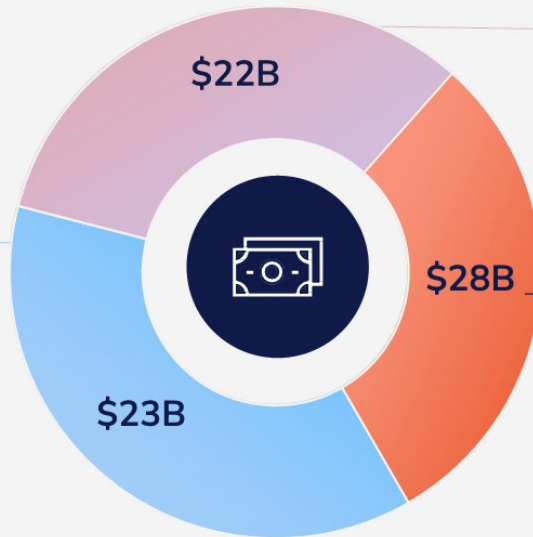
A full ecosystem solution: Hardware, software, consumables and applications powered by artificial intelligence

Imaging, Sensing, and Guided Intervention are Large Markets Poised for Disruption

Estimated \$70+ billion opportunity across the ecosystem



Imaging
Hospitals, Outpatient
>100,000
Potential installation targets



Sensing
ICUs, Expanded Hospital,
Surgical Centers, Outpatient,
At-home
~4M
Potential unit sales



Guided Intervention
Hospitals and Health Systems
>50M
Potential image guided
procedures

We are Transforming Medical Imaging with Swoop®

Swoop is the world's first FDA-cleared portable MRI system™



MRI 1.0
1980



MRI 2.0
1990



MRI 3.0
FDA Cleared 2020

HYPERFINE

Swoop® is the Next Generation of MRI

Patent protected noise cancellation system enables clinical-grade images



Portable low-field MRI



FDA Cleared in 2020



Reimbursed under existing imaging codes:
MRI Brain without Contrast: 70551



Installed base of **70 units***
as of year-end 2021



Current primary clinical uses:

- Hydrocephalus and Pediatrics
- Neuro ICU Follow-Up and Post-Operative
- Stroke



*Installed base includes commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations

HYPERFINE

Swoop® Brings MRI to the Patient



Acute Care Settings



Intensive Care Units
and Operating Rooms



Global Health

- Swoop is designed to enable **rapid diagnoses and treatment** for patients regardless of income, resources, or location
- Produces **high-quality images at low magnetic field strength**, allowing clinicians to quickly scan, diagnose, and treat patients
- Wheeled **directly to a patient's bedside**, plugged into a **standard electrical wall outlet**, and **controlled by an iPad®**

HYPERFINE

Clinical & Workflow Benefits

HYPERFINE



Adverse events occur in
22-46%
of cases
during transport

Numerous challenges with conventional MRI :

High-cost limits accessibility



Complex site requirements and upgrades



Scheduling delays lead to longer length of stay



Consumption of valuable personnel resources



Risk of adverse events during transportation



Maintaining connection to life support equipment



Hyperfine Workflow Benefits



Traditional MRI workflow (25.8 hours)



Hyperfine workflow (90mins, 94% reduction in total workflow time)



Swoop Clinical Use Cases Today

Intensive Care Unit

- Acute Mental Status Change
- Ataxia
- Cerebral Edema
- Cerebrovascular Disease
- Cranial Neuropathy
- Extra Ventricular Drain Placement
- Follow-up Intracranial Hemorrhage
- Follow-up Ischemic Stroke
- Follow-up Hematoma
- Stroke
- Tumor Pre- and Post-Op

Emergency Department

- Blurred Vision
- Cranial Neuropathy
- Dizziness
- Headache
- Numbness
- Stroke
- Tingling
- Traumatic Brain Injury
- Vertigo
- Weakness

Rehabilitation Clinic

- Acute Mental Status Change
- Brain Injury After Fall
- Stroke Recovery

Outpatient

- Atrophy Monitoring
- Hydrocephalus (Shunt Check)
- Multiple Sclerosis

Pediatric

- Brain Volumetrics
- Hypoxic Ischemic Encephalopathy
- Hydrocephalus (Dx and Monitoring)
- Sports Injury
- Suspected Abuse

HYPERFINE

Clinical Validation of Hyperfine



Game changer is a good way to put it [...] being able to do the level of sophisticated imaging in an ICU that MRI can provide.”

Dr. Fady Charbel, MD, FAANS, FACS



Hyperfine provides me with an opportunity to acquire the information, to interpret the information, and to make a decision based on the information that's in front of me.”

Dr. Shahid Nimjee, MD, PhD, FAANS, FAHA



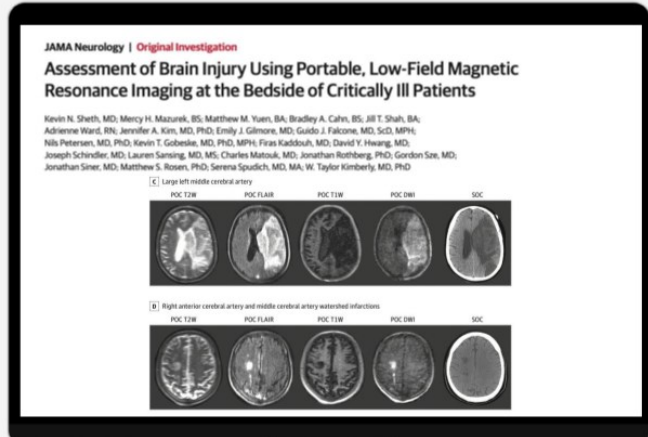
Portable MRI should be used to image any patients in ICUs in any [clinical] setting.”

Dr. Michael Schulder, MD, FAANS



Over 25 conference presentations and publications discussing clinical benefits for:

Stroke | Hydrocephalus | Hematoma | Multiple sclerosis | Tumor resection



Use Case: Stroke

HYPERFINE

Hyperfine Provides Compelling Platform for Stroke Diagnosis

15 million

people worldwide suffer a stroke annually



MRI scans are better at **detecting ischemic stroke damage** compared to CT scans



Stroke is the **2nd leading cause of death** globally



MRI use for stroke has been limited due to **lack of access** to this expensive equipment and experienced neuroradiologists to interpret the results.



87% strokes are ischemic strokes



Hyperfine offers an affordable MRI platform that can perform **diffusion imaging**

for stroke diagnosis at the patient's bedside, images can be shared securely with neuroradiologists around the world



HYPERFINE

Stroke Diagnosis Confirmed

62-year-old male

Presented with new left sided weakness and tremor



HYPERFINE

Use Case: Hydrocephalus

HYPERFINE

Radiation Exposure and Imaging Access for Hydrocephalus Shunt-Checks is an Overlooked Problem

Hydrocephalus:

The **buildup of fluid in ventricles**, treated with shunt placement.

Any symptoms **cause trips to hospital for a shunt check.**



Problem:

Children can receive **1-12 CTs¹ each year**, increasing their risk for radiation-associated malignancy²

High field **MRI is generally more resource intensive and expensive** to perform than CT

50% of shunts **fail in <2 years** and **98% of shunts fail by year 10.**³



US Market:

36,000 shunt surgeries in the US each year⁴

2 scans/patient/year for shunt follow-up¹

*1: <https://link.springer.com/article/10.1007/s00381-019-04345-3> | *2: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6166961/> | *3: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7053664/> | *4 <https://www.hydroassoc.org/powerful-facts/>

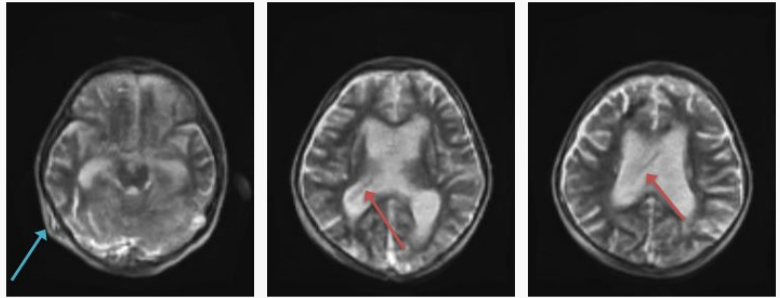
Hydrocephalus: Swoop's Potential from Early Cases

“

Hyperfine is a fit in the neurosurgery clinic to screen hydrocephalus patients. The cost of the machine is not prohibitive so you could have one of these in each of the neurosurgery clinics and it would probably pay for itself if you did a few a week

-Radiologist

”



5 y/o presents to Neurosurgery clinic with headache. Swoop scan performed in the clinic demonstrates ventricular catheter (without artifact from valve) along with enlarged ventricles – child admitted to hospital for shunt revision immediately, saving radiation and delay.

HYPERFINE

Pipeline Opportunities

HYPERFINE

Innovative R&D Engine Designed to Expand Product Roadmap

Potential benefits:

 <p>Improved usability</p>	 <p>Expanded Addressable Market</p>
 <p>Lower cost of goods</p>	 <p>Automated Stroke Detection</p>



Developing a Non-Invasive Brain Vital Sensor

Breakthrough AEG™ Technology designed to unlock access to blood flow and pressure



Non-Invasive

Non-invasive use on every patient to enable broader access and earlier diagnosis



Continuous Trend Analysis

Designed for continuous sensing to build trends for data-backed treatment



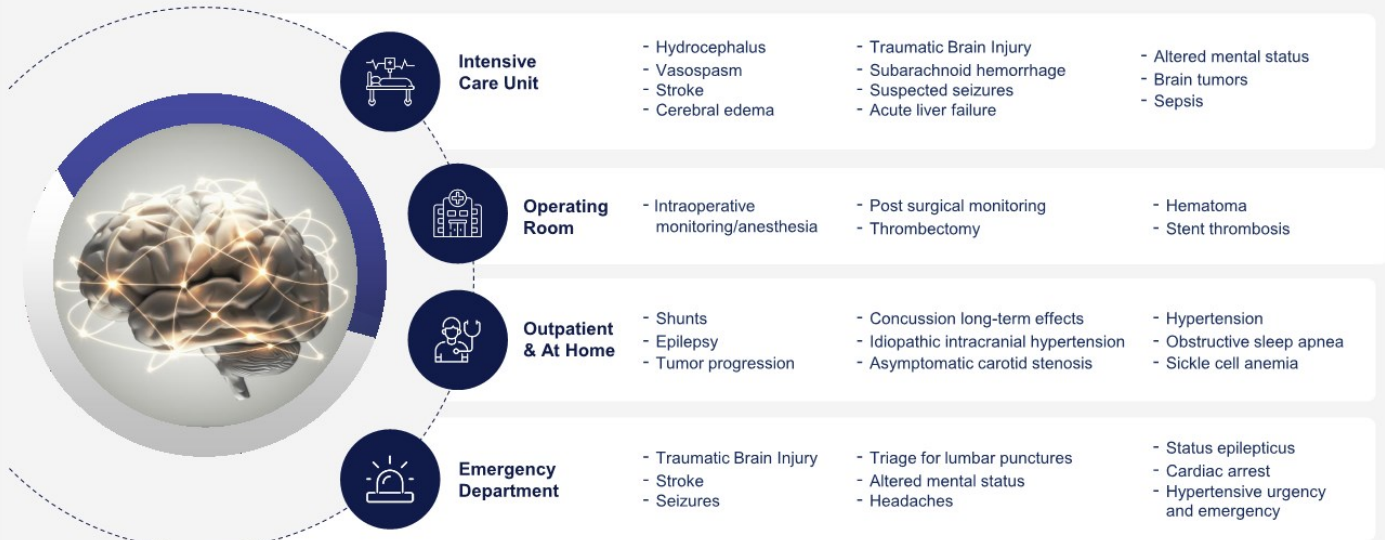
Easy to use

Designed to be easy to use for immediate, precise care

*The first AEG™ device is being developed, subject to regulatory authorization, to aid in the diagnosis and management of brain disorders through the development of novel acoustic sensing techniques and innovative algorithms for measuring key metrics of brain health.

HYPERFINE

Brain-Sensing Clinical Opportunities



Financial Profile

HYPERFINE

2021 Preliminary Financial Results* & Total Installed Units

- Approximately \$1.42 to \$1.50 million preliminary unaudited 2021 total revenue
- Realized approximately \$1.45 million in grant funding for the full year 2021 as part of grant fulfillment for Swoop installations

TOTAL INSTALLED UNITS						
	2020	2021				TOTAL
		Q1	Q2	Q3	Q4	
Commercial Systems Installations	4	5	7	4	7	27
Grant Fulfillment Installations	0	2	2	4	10	18
	4	7	9	8	17	45
Research Units	15	2	2	3	3	25
Total Installed Units	19	9	11	11	20	70

*See slide above titled "Preliminary Financial Information" for important information about our preliminary unaudited financial information.

**The Swoop total installed base consists of three components: Commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations. The Swoop total installed base (or total installed units) is the number of Swoop devices deployed to hospitals, other healthcare providers, and research institutions.

HYPERFINE

2021: A Milestone Year

- **July:** Announced Definitive Agreement to be Listed on Nasdaq through a Business Combination with HealthCor Catalio Acquisition Corp.
- **August:** Swoop® Demonstrates High Accuracy for Detection of Brain Hemorrhage in Study Published in Nature Communications
- **September:** Announced Plans for Global Expansion Starting with Launches in the United Kingdom and Pakistan
- **September:** Announced Receipt of Additional \$3.3 Million Grant from Bill & Melinda Gates Foundation to Improve Access to Neonatal and Pediatric Brain Imaging in Low-Resource Settings Globally
- **November:** Received FDA Clearance for Deep Learning Portable MRI, Defining the Future of Life-Saving Diagnostics
- **December:** Announced Expansion into Canadian Market with Medical Device License Issued by Health Canada
- **December:** Closed Business Combination with HealthCor Catalio Acquisition Corp. and Liminal Sciences, Began Trading under the Ticker "HYPR" on the Nasdaq Global Market

HYPERFINE

Leadership Team

HYPERFINE

Management Team with Proven Track Record of Success



Dave Scott
Chief Executive Officer



Alok Gupta
Chief Financial Officer



Dr. Khan Siddiqui
Chief Strategy Officer &
Chief Medical Officer




Tom Teisseyre
Chief Product Officer




Mark Hughes
Chief Operating Officer



Scott White
Chief Commercial Officer



Kyla Pavlina
Chief People Officer



Neela Paykel
General Counsel

Thank You!



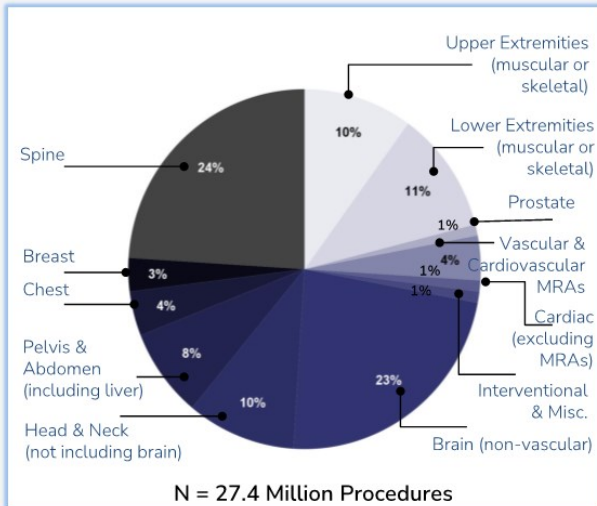
HYPERFINE

Appendix

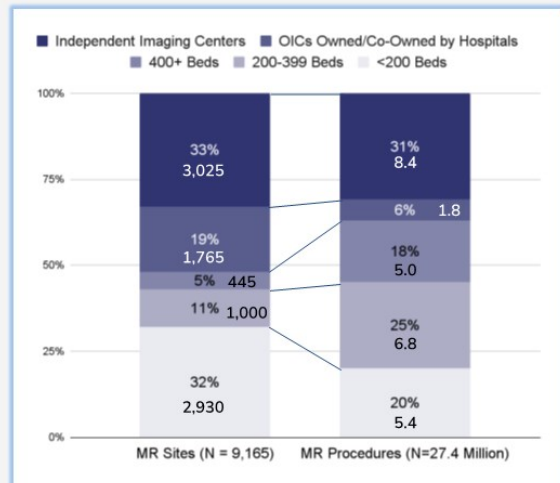
HYPERFINE

Brain is the Largest MRI Market with Nearly 25% of MR Procedures

MR Procedure Mix, All Sites, by Percent, 2020



Distribution of MR Sites and Procedures, by Site Type, 2020



*Source: 2020 IMV MR Benchmark Report