

**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): **March 09, 2022**

Hyperfine, Inc

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39949
(Commission File Number)

98-1569027
(IRS Employer
Identification No.)

351 New Whitfield Street
Guilford, Connecticut
(Address of Principal Executive Offices)

06437
(Zip Code)

Registrant's Telephone Number, Including Area Code: 203 458-7100

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

From time to time, Hyperfine, Inc. (“Hyperfine”) presents and/or distributes slides and presentations to the investment community to provide updates and summaries of its business. On March 9, 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 year ended December 31, 2021, and other information about Hyperfine’s business.

Item 7.01 Regulation FD Disclosure.

The corporate presentation updated on March 9, 2022 also include information about Hyperfine’s business and operations. This corporate presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 No.	Description
99.1	Corporate Presentation of Hyperfine, Inc. dated March 9, 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 thereunto duly authorized.

HYPERFINE, INC.

Date: March 9, 2022

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



HYPERFINE

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

Corporate Presentation | March 2022

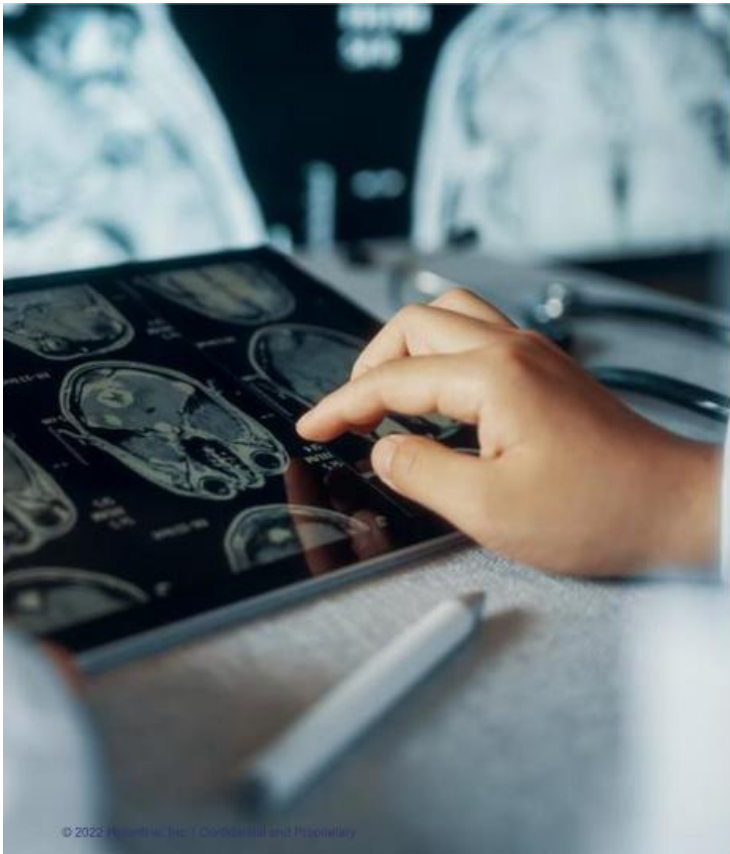
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Forward Looking Statements

This presentation 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, Hyperfine's expectations with respect to financial results, future performance, development and commercialization of products and services, the potential benefits and impact of Hyperfine's products and services, potential regulatory approvals, and the size and potential growth of current or future markets for Hyperfine's products and services. 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.

Preliminary Financial Information

The preliminary financial information included in this presentation 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.



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
(exploratory)



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

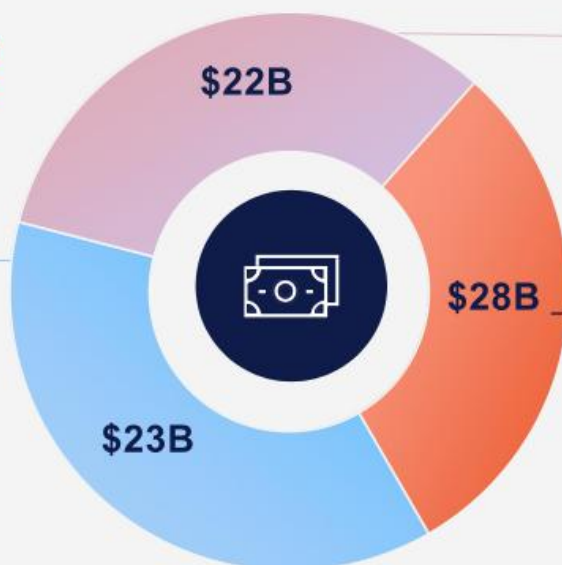


Imaging

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

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

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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®**

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 (90 mins, 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



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



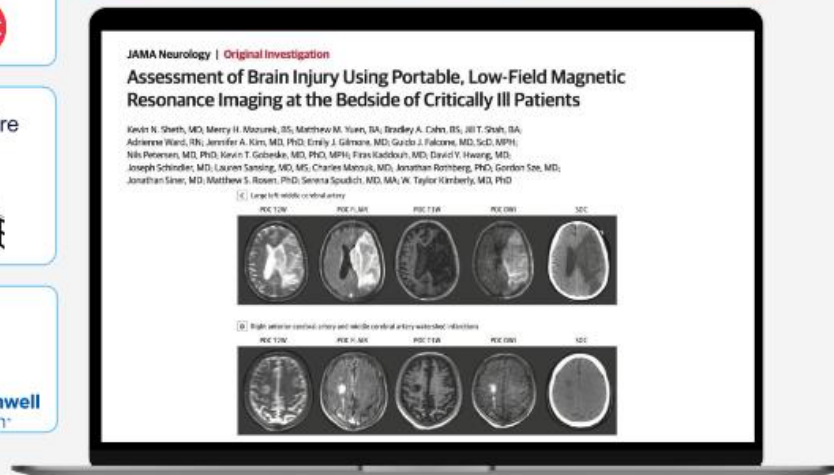
Portable MRI should be used to image any patients in ICUs in any [clinical] setting.”

Dr. Michael Schulder, MD, FAANS



Over 40 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



Use Case: Hydrocephalus

HYPERFINE

Pediatric Hydrocephalus Management is a Huge Problem

~400,000 hospital days, \$2B in hospital charges in the US



Children with hydrocephalus need **life-long monitoring** and use a disproportionate number of hospital days and **resources**.^{1, 2}



Children can receive **1-12 CTs⁵ each year**, increasing their risk for radiation-associated malignancy⁶. Rapid MRI (T2 only) is preferred since it's radiation free but may not be available.



Any symptoms cause trips to hospital for a shunt check to ensure pressure on the brain remains normal. **50% of shunts fail in <2 years and 98% of shunts fail by year 10.**^{2,3, 4}



Swoop helps overcome existing workflow barriers to enable safe and timely imaging at the point of care with an improved patient experience.

1. <https://hins.org/foia/view/journals/neuro-soc/27/5/article-11E5.xml>

2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6166861/>

3. <https://www.hydroassoc.org/condition/shunt-not-working/>

4. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Hydrocephalus>

5. <https://link.springer.com/article/10.1007/s00381-019-04745-3>

6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6166861/>

7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7053864/>

8. <https://www.hydroassoc.org/powerful-facts/>

Personal Stories from the Hydrocephalus Association



Vacations can involve **traveling with CD's and notebooks with prior scans.**



At home, we keep a suitcase packed to keep our child entertained during the **long wait time in the ED for imaging and hospital stay.**



Received so many CT scans that we're waiting on a cancer diagnosis. **No radiation.. swoop is like a parents dream.**



Hydrocephalus Workflow Improvement with Swoop®

Traditional workflow results in delayed diagnosis and potential radiation exposure



Hyperfine allows kids to be imaged sooner, next to their loved ones, **without radiation**



Hydrocephalus: Swoop's Potential from Early Cases



Hyperfine is an excellent addition to the neurosurgery clinic for screening of hydrocephalus patients. The convenience for the patient, reduced scan time, and cost of the machine make this a device that should be considered for any neurosurgery clinic.

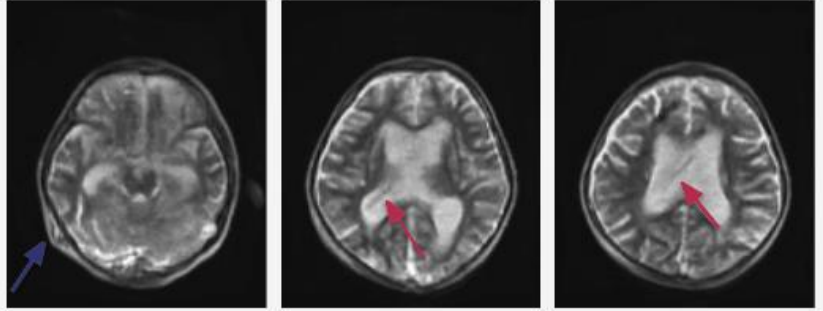


Jeff Leonard, MD
Chief of Neurosurgery



**NATIONWIDE
CHILDREN'S**

When your child needs a hospital, everything matters.



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.

Use Case: ICU Serial Imaging

HYPERFINE

Patient Delays to Transfer in the ICU Creates Major Unnecessary Costs for Hospitals, is “Common and Costly”

Estimated \$300/hr for delays, >\$22,000/week for hospital (>\$1M/year) for large academic center

Imaging capabilities of MRI, CT and Ultrasound **should be available 24/7/365** at all facilities.

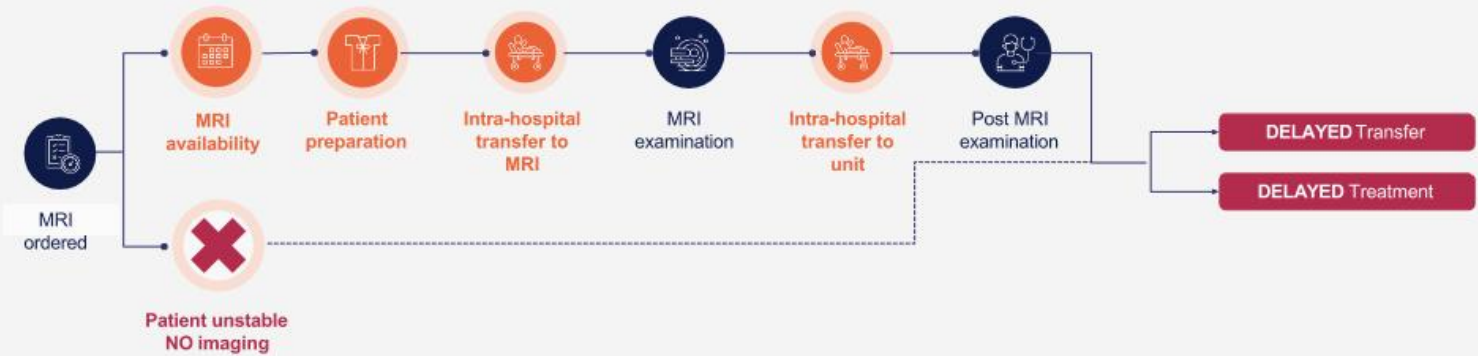
In reality, patients can **wait more than 24 hrs for MRI availability**, resulting in cost for both the patient and the hospital, taking up an ICU bed.



If only there was a way to improve access to imaging....

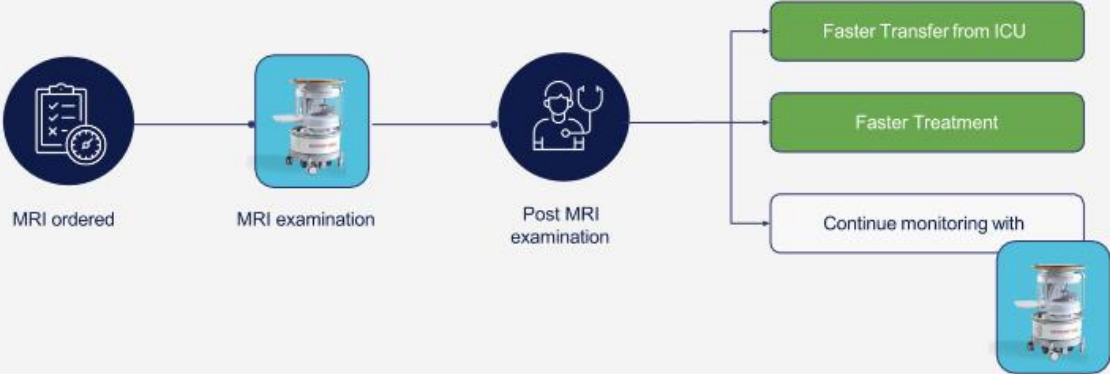
Current ICU Imaging Workflow with Conventional MRI

Traditional MRI workflow can lead to **prolonged delays** in patient care and **higher resources consumption**



Improved ICU Imaging Workflow with Swoop

Portable MRI workflow enables **timely care** for earlier discharge by bringing brain imaging to the patient's bedside



Swoop's Potential Benefits in the ICU



Reduced time to diagnosis

Swoop workflow is significantly faster than conventional MRI



Reduced patient care interruption

Transport time (2-3 hours) interrupts patient care and impacts staffing for entire ICU¹



Reduced adverse events associated with patient transport

Adverse events occur in up to 46% of transported patients.



Reduced costs associated with length of stay

Shortening time to diagnosis, avoiding interruptions in care, and preventing adverse events



Optimized staffing in the ICU

Time consuming transport affects ICU staff: nurse, respiratory therapist, anesthesia, transport, and practitioner.



Reduced exposure to ionizing radiation

Ionizing radiation from CT used for serial follow-up scans = risk to patient and staff

¹ Hyperfine, Care Area - Acute Mental Status Change, Page 1a

Clinical Settings Growth

Today's use cases provide a sizeable opportunity and platform for growth.



Pipeline Opportunities

HYPERFINE

Innovative R&D Engine Designed to Expand Product Roadmap

Potential benefits:



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

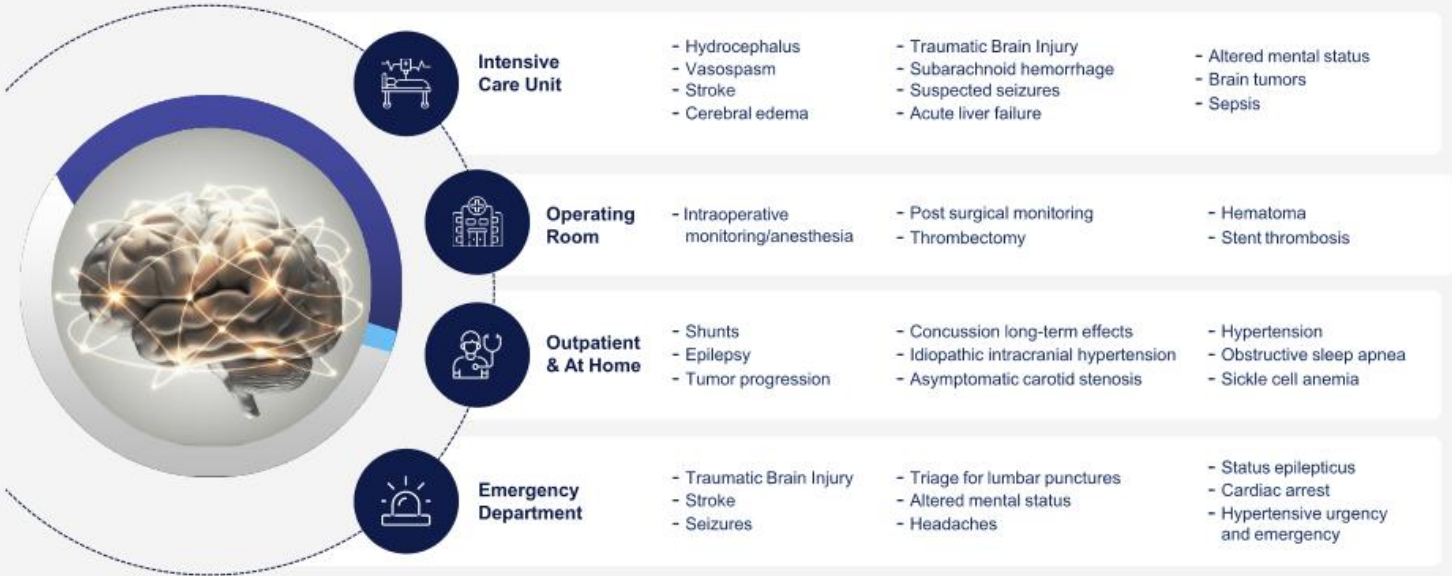
Designed to be easy to use for immediate, precise care

*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.

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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.

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2021 & 2022: Major Accomplishments

- **July 2021:** Announced Definitive Agreement to be Listed on Nasdaq through a Business Combination with HealthCor Catalio Acquisition Corp.
- **August 2021:** Swoop® Demonstrates High Accuracy for Detection of Brain Hemorrhage in Study Published in Nature Communications
- **September 2021:** Announced Plans for Global Expansion Starting with Launches in the United Kingdom and Pakistan
- **September 2021:** 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 2021:** Received FDA Clearance for Deep Learning Portable MRI, Defining the Future of Life-Saving Diagnostics
- **December 2021:** Announced Expansion into Canadian Market with Medical Device License Issued by Health Canada
- **December 2021:** Closed Business Combination with HealthCor Catalio Acquisition Corp. and Liminal Sciences, Began Trading under the Ticker "HYPR" on the Nasdaq Global Market
- **January 2022:** Placed Swoop system with Minnesota Medical Center to Grow its Advanced Imaging Systems Offering
- **February 2022:** Appointed Chip Truwit, M.D. as Senior Medical Director
- **February 2022:** Placed Swoop system with Queen's University Radiology to Improve Access to Care for Canadian Patients in Remote Northern Communities

incubateD
PITCH COMPETITION

HYPERFINE

Named by Fierce Medtech
as one of 2020's

FIERCE
MedTech
FIERCE 15



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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!



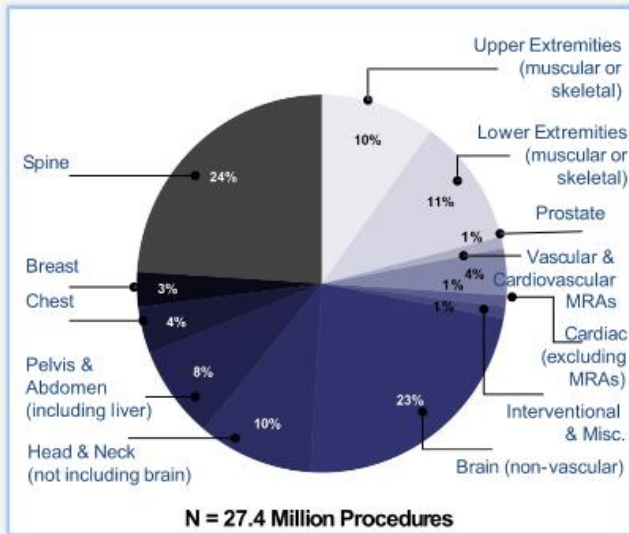
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Appendix

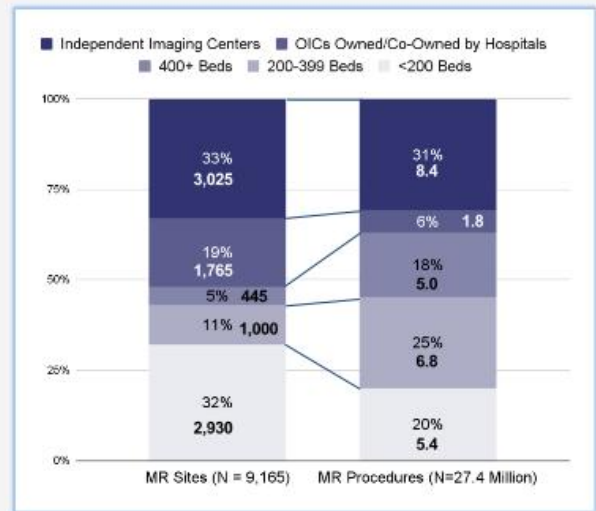
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Brain is the Largest MRI Market with Nearly 25% of MR Procedures

MR Procedure Mix, All Sites, by Percent, 2020



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



*Source: 2020 IMV MR Benchmark Report
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