

smarHER MRI is the first end-to-end software to use AI technology to provide intuitive and unbiased guidance for fibroid surgeries.

MARKET OPPORTUNITY

Every year in the U.S. there are more than 600,000 hysterectomies and 30,000 myomectomies. As of 2019, the uterine fibroid treatment device market was valued at \$4.6 billion and is expected to grow at a 9.5% CAGR from 2020 to 2027 (Grand View Research).

TECHNOLOGY & PRODUCT

smarHER MRI software incorporates 2 main technologies, deep learning algorithms and mixed reality displays. Leveraging the wealth of data from Weill Cornell Medicine, deep learning models are generated that automate the segmentation of anatomic and pathologic gynecologic structures. These structures can be viewed on conventional 2D monitors or using 3D virtual, augmented, or mixed reality headsets. The software allows for pre-operative path planning to aide in procedural efficiency and patient consultations. Adherence to the plan is achieved by providing step-by-step, 3D guidance during the procedure, thus providing better outcomes for patients.

Currently, there exists commercial segmentation software that can manually produce the 3D renderings to be exported into a real-time 3D development platform (e.g., Unity) for visualization in virtual, augmented, or mixed reality. However, this manual process is too tedious and time-consuming for a healthcare professional to perform and, therefore, they continue to use standard MRI viewers. Unfortunately, the MRI viewers provide non-intuitive visualization that is nearly impossible for a patient to fully comprehend the complexity and significance of their pathology and disease state. By enabling an automated end-to-end software, physicians can provide the best care to their patients by clearly showing their anatomy in 3D, the procedural plan, and their ability to stick to that plan.

BUSINESS MODEL

smarHER will be a software as a service (SaaS), charging for each case that will produce a 3D rendering.

INTELLECTUAL PROPERTY

smarHER will license from Weill Cornell Medicine its provisional patent as well as the annotated data libraries of MRI scans, as well as the know-how related to the development of the smarHER technology.

REGULATORY

The smarHER system is anticipated to be a Class 2 system and fall under the 510(k) regulatory path. As the product is not a decision support tool, a clinical trial will likely not be required. However, an IRB has already been approved to perform a pilot study at Weill Cornell Medicine using the commercial prototype software. The trial is expected to provide evidence that the system improves both patient understanding and procedure outcomes.

MANAGEMENT

Tamatha Fenster, M.D., Co-Founder

- Director of Biotechnology and Innovation, Fibroid and Adenomyosis Center
- Asst Professor of Obstetrics & Gynecology, Weill Cornell Medicine, New York Presbyterian
- Creator of VoiceLove, a 2-way device used to communicate with loved ones in ICU

Bobak Mosadegh, Ph.D., Co-Founder

- Associate Professor of Biomedical Engineering in Radiology, Weill Cornell Medicine

AWARDS

- M2D2 Competition (April 2021) – Asahi-INTECC and Hologic In-Kind Awards
- Co-First Place, Medical Devices, BioVenture eLab Business Plan Challenge (May 2021)



LOCATION: New York, NY

STRATEGIC PARTNERS:

Weill Cornell Medicine/NYP
Hologic

SCIENCE ADVISORS

Robert Troiano, M.D., Associate
Professor of Radiology and Clinical
Obstetrics and Gynecology, WCM

BUSINESS ADVISORS

Jahanara Ali, Ph.D., Director of
Bioventure eLab, WCM

Yaron David, Entrepreneur-in-
Residence, WCM

FINANCING TO DATE

\$50K Hologic In-Kind Services
\$25K BioVenture eLab Proceeds

SEEKING \$1.6M SEED

Proceeds to be used for prototype
development, 100-pts pilot study,
and working capital purposes



Candidate Profile Chief Executive Officer

Location: New York, NY (remote possible)

Position: Full-time Preferred / Part-time Considered

smartHER, Inc. (smartHER) is a mixed reality (MR/AR)-based medical device company focused on developing innovative solutions for gynecologic procedures, with an initial focus on rehauling how MRI scans are utilized for uterine fibroid removal. The company is spinning out of Weill Cornell Medicine (WCM) where it has gained significant traction by developing a MVP. It has received multiple awards for its novel product design, established strategic partners in several relevant domains (e.g., women med device, cloud computing, and MR software), and is in the process of validating the technology through a clinical study.

smartHER is looking to hire its inaugural Chief Executive Officer (CEO). The CEO will work with the academic founders in all aspects of in-licensing from WCM, fundraising, team building, developing and executing the strategic plan, and shaping the company's future success. The CEO has the primary responsibility for managing the organization's day-to-day activities, financial plan and operations, leading the organization's fundraising, directing and coordinating the work of professional staff, and serving as its primary ambassador and spokesperson. Working with and reporting to the to-be-formed Board of Directors, the CEO will ensure that the organization's R&D activities and operations meet the needs and interests of its various stakeholders.

Who you are:

- You are comfortable working in a startup environment and have a demonstrated ability to attend to multiple priorities without losing focus of the company's long-term goals.
- You have strong analytical and organizational skills to set strategy and translate strategy into tactics.
- You overcome obstacles collaboratively while respecting others' points of view, and you empower your fellow team members to be creative and resourceful.
- You strive to be a thought-leader, are always learning, and are always well-informed on the state-of-the-art in your discipline.
- You are internally motivated to implement best practices in a continuous cycle of improvement.
- You can inspire, coach and lead project teams to meet project deadlines.

Opportunity:

- Create a radically new visualization system and improve patient care for those suffering from uterine fibroids.

- Lead the success of a medical device startup with cutting edge technology and Ivy-league pedigree.
- Build an open, meritocratic, data- and results-driven culture.
- Attract/select your team members and manage them to hit corporate goals.
- Expect the highest professional standards and share in rewards for meeting deliverables.

Responsibilities:

- Work closely with the academic founders to drive corporate strategy and long-range plans, including product development and financing strategies.
- Lead fundraising efforts with investors and secure the necessary resources for the organization to meet its goals and objectives.
- Identify, evaluate, negotiate and complete significant contracts, including potential partnering, in-licensing, and out-licensing.
- Cultivate a strong and effective partnership with product development and regulatory teams and manage the clinical trial process.
- Monitor competitive intelligence by keeping up to date on market trends, competitors and opportunities.
- Provide regular presentations in various forums and partner with the team to deliver on an annual strategy and forge a view into future growth opportunities for the company.

Qualifications:

- Advanced scientific degree preferred; Candidates with experience in software as a medical device, medical imaging, deep learning, and/or mixed reality, preferred. MBA is a plus.
- 15+ years of working experience in medical devices with recent experience leading teams and bringing products through pre-clinical, IDE and early clinical stages of development.
- Proven track record of identifying opportunities and structuring, negotiating and closing transactions including equity investments, strategic operating alliances, licensing agreements, and/or joint ventures.
- Exceptional communication and influencing skills with the ability to inspire confidence and work successfully with varied audiences including Board of Directors, investors, financial institutions, industry partners, fellow management, and employees.
- Entrepreneurial, collaborative, energetic self-starter with strong interpersonal and analytical skills.
- Strong interpersonal skills that include excellent skills in written communication, oral communication, collaboration, and problem solving with other colleagues.
- Unwavering determination with appropriate actions to make the company successful; working well under pressure while maintaining a professional demeanor.
- Ability to travel to attend meetings, key business engagements and investor meetings.

Compensation:

- Equity incentives commensurate with the risks of a startup.
- Salary with bonus (likely paid only after funds are raised; accrued in interim period).
- Benefits determined based on financial resources.