

Imaginostics, Inc.

Category:

Best Startup

Company Name:

Imaginostics, Inc.

Turnover and/or Funding:

Funding Raised:

2018: \$400K from angel investors, led by clinician investors

2020: \$100K (primarily in-kind IP services) from IDEASHIP Fund (VC)

2021: \$516K from angel investors, led by clinician investors

2022:

\$725K from the Alzheimer's Drug Discovery Foundation (ADDF; dilutive)

\$435K from NIH (NIMH; non-dilutive)

\$915K from NIH (NIA; non-dilutive)

2024: \$5.3M from angel investors, led by clinician investors

Total Funding to Date: ~\$8.4M (including \$1.35M non-dilutive)

Sub-Category:

Medical Technology / Digital Health

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

Imaginostics was co-founded by Dr. Codi Gharagouzloo and Valerie Gharagouzloo, uniting their expertise in science, innovation, and entrepreneurship. Dr. Gharagouzloo identified significant shortcomings in conventional MRI technologies, specifically the

reliance on qualitative image interpretation and the toxicity associated with gadolinium-based contrast agents. Driven by a vision to transform medical imaging, he pioneered quantitative imaging techniques leveraging ultrashort time-to-echo (UTE) MRI sequences combined with iron oxide nanoparticle-based contrast agents, enabling safer and more precise vascular imaging.

Valerie Gharagouzloo, an accomplished attorney and entrepreneur, founded her law practice, ArkSwan Legal PLLC, at the Cambridge Innovation Center, focusing on providing accessible legal services to underserved communities. Her deep expertise in business development, operational strategy, and legal affairs significantly shaped Imaginostics' early trajectory. Initially supporting Imaginostics part-time, Valerie fully joined as Chief Operating Officer in 2023 and transitioned to Chief Executive Officer in early 2025, spearheading strategic direction, driving commercialization efforts, and expanding key industry partnerships.

Initial clinical validation of the quantitative imaging technology was conducted at Massachusetts General Hospital during Dr. Gharagouzloo's postdoctoral research, transitioning the technique from animal models (mice and rats) to primate and human studies. After founding Imaginostics, further refinement of the prototype was pursued in collaboration with Dr. Peder Larson at the University of California, San Francisco (UCSF). Despite early fundraising challenges compounded by the COVID-19 pandemic, Imaginostics gained substantial momentum through a series of grants and investments, including NIH grants totaling approximately \$1.35 million from the National Institute on Aging (NIA) (\$915.9K) and the National Institute of Mental Health (NIMH) (\$436.6K), alongside strategic investment from the Alzheimer's Drug Discovery Foundation (ADDF) (\$725K).

In June 2024, Imaginostics completed a substantial Seed Round of \$5.3 million with Clinician Business Angels, marking a significant milestone and reflecting robust investor confidence. Earlier funding rounds also included seed investments from Clinical Angels totaling over \$1 million.

In 2024, Imaginostics achieved a major regulatory breakthrough, securing the FDA Breakthrough Device Designation. This recognition underscored the innovative and clinically significant potential of the company's quantitative imaging platform. Strategic hires bolstered technical leadership, notably appointing Dr. Scott Hoge from Brigham and Women's Hospital as Chief Technology Officer and Dr. Chenguang Zhao as VP of Engineering, an outstanding pulse sequence specialist from Philips, enhancing the company's technical capabilities and industry expertise.

Imaginostics' innovative contributions have been recognized through multiple prestigious awards, including the 2025 Young Alumni Impact Award, the Illumination Awards Entrepreneur of the Year, and the Innovation Winner at the 2024 FAB Awards. The company has prominently showcased its technology at renowned industry forums such as the Florida Venture Capital Conference, Biotech Showcase, Hello Tomorrow, MassChallenge, French Tech Capital Days, and BioPitch.

Currently, Imaginostics is actively forming strategic partnerships with leading medical device vendors and healthcare institutions, and a renowned drug manufacturer propelling the company toward pivotal Phase 3 clinical trials. With a steadfast

commitment to enhancing diagnostic accuracy, patient safety, and clinical outcomes globally, Imaginostics continues to lead the advancement of next-generation imaging solutions.

History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):

QUTE-CE MRI integrates advanced 3D excitation with rapid radiofrequency (RF) pulses and captures MRI signals approximately 1000 times earlier than traditional sequences, generating images with signal intensity accurately predicted by fundamental physical equations before susceptibility-induced signal modulation occurs [1]. Conventional MRI techniques for measuring vascular structure, function and leakage do not work at the individual level, positioning QUTE-CE as the only truly precision diagnostic vascular imaging modality available today.

Extensive preclinical studies have underscored the quantitative precision and versatility of QUTE-CE MRI. These include demonstration of minimal errors in contrast-agent concentration measurement [1], precise 3D mapping of small and large vessel density (vasculome) [2], and high sensitivity in detecting early structural abnormalities in microvascular density within the APOE4 rat model relevant to Alzheimer's disease [3]. Further, QUTE-CE MRI accurately measures functional cerebrovascular reactivity (CVR) responses and neuro-pharmaceutical impacts in small animal models [2]. Notably, this modality also precisely quantifies blood-brain barrier (BBB) leakage at the individual animal level following mild head impacts [4] and in rat models of type 2 diabetes [5]. Additionally, QUTE-CE MRI effectively assesses vessel permeability in subcutaneous tumor models, providing critical insights into treatment efficacy [6]. QUTE-CE MRI has also elucidated new mechanisms of cerebral waste clearance relevant to neurological health and disease [7], and studies have demonstrated its ability to detect subtle physiological variations in glymphatic system function influenced by the circadian cycle [8].

Clinically, QUTE-CE MRI has shown substantial advantages over standard gadolinium-based contrast agent (GBCA) MRI. In a comparative pulmonary thoracic imaging study of 20 subjects scanned with both modalities, radiologists reported superior vessel delineation and a 10-fold improvement in visualization of soft tissues and other structures [9]. Similarly, neuroimaging studies demonstrated at least 10-fold improvements in signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) compared to conventional ferumoxytol-enhanced MRI, further emphasizing its superior imaging capability [10, 11]. Given its efficacy and potential for safer imaging, QUTE-CE MRI received FDA Breakthrough Device Designation in 2024 as a replacement for GBCA MRI and iodine-based CT imaging, addressing over 2 million annual scans in the U.S. for patients with CKD stages 3-5.

Imaginostics holds robust intellectual property protections covering its core technology and various applications. Initial innovations in QUTE-CE MRI were developed at

Northeastern University, leading to foundational patents including U.S. patent number 12,121,339 (nationalized application 15/747,202), granted on October 22, 2024, from original PCT application PCT/US2016/036606, published as WO2017019182A1, and also nationalized in the EPO (application EP16830977.1, pending). Additional pending PCT applications address targeted medical applications such as central nervous system and brain disorders (PCT/US2020/015223), dementia (PCT/US2019/044001), and blood-brain barrier leakage (PCT/US2020/012191). Furthermore, Imaginostics holds exclusive licenses to additional patents from the University of Wisconsin (WARF), notably U.S. patents US 9,274,193 for MRI data acquisition and US 10,338,180 for MRI data filtering. Imaginostics' technology has been developed through strategic collaborations with prestigious institutions including Northeastern University, Massachusetts General Hospital, University of California San Francisco (UCSF), and the University of Wisconsin, which have significantly contributed to the advancement, validation, and clinical translation of QUTE-CE MRI.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Chronic diseases often start silently, with subtle changes in microvasculature and tissue metabolism [12-14]. These early changes occur in the smallest blood vessels (capillaries, arterioles, venules) and play a pivotal role in disease progression. In diabetes, microvascular damage leads to complications like retinopathy, nephropathy, and neuropathy [15-17]. Hypertension begins with small vessel remodeling before clinical symptoms manifest [18]. Alzheimer's disease involves early microvascular dysfunction and blood-brain barrier leakage [19], while chronic kidney disease progresses from glomerular microvascular impairment [20].

Many chronic diseases, regardless of their initial causes-immune dysregulation, genetic mutations, cellular errors, or mechanical stress-ultimately impact microvasculature and metabolism, perpetuating disease progression.

Detecting these early changes quantitatively, non-invasively, and safely is vital for timely diagnosis and effective therapeutic intervention. Traditional MRI, however, is often qualitative, artifact-prone, uses potentially toxic contrasts, and lacks reliability. QUTE-CE MRI introduces a transformative imaging innovation by:

- **FDA Breakthrough Designation:** Recognized by the FDA as a breakthrough technology for imaging in patients contraindicated for gadolinium and iodine contrast, underscoring its significant clinical and technological advancement.
- **Improving Safety:** Employing iron-based contrast agents, avoiding the toxicity risks associated with gadolinium, particularly important for vulnerable patient groups and longitudinal studies.
- **Reducing Artifacts:** Using Ultra-short Echo Time (UTE) sequences for clearer imaging near air-tissue or bone interfaces, including imaging around and within metallic implants such as stainless steel-typically challenging with conventional MRI and CT.
- **Enhancing Imaging Quality:** Providing 10x higher signal-to-noise ratio (SNR) and

2-3x higher resolution, clearly visualizing microvascular structures.

- **Quantitative Biomarkers:** Delivering the first precision diagnostic imaging biomarkers that reliably reflect microvascular health, perfusion, and tissue metabolism at the individual patient level.

- **Increasing Throughput:** Allowing ferumoxytol infusion hours before imaging, eliminating timing constraints typical with gadolinium or iodine-based imaging. This reduces scanner occupancy time by approximately half, enables off-scanner allergic reaction monitoring for enhanced safety, and facilitates parallel workflows, effectively doubling contrast-enhanced imaging throughput without hardware modifications.

Broad Implications for Research and Human Health

QUTE-CE MRI bridges the gap between early biological changes and clinical manifestations, enabling:

- **Earlier, Accurate Diagnoses and Pre-symptomatic Detection:** Identifying subtle changes in high-risk individuals before overt symptoms arise.
- **Real-Time Monitoring:** Supporting precise diagnosis, treatment planning, treatment monitoring, and predicting, preventing, and assessing off-target toxicity.
- **Enhanced Mechanistic Research:** Clarifying the vascular basis of chronic diseases.
- **Accelerated Drug Development:** Providing imaging-derived biomarkers to evaluate therapeutic efficacy, including unique assessment of inflammation through vessel leakage-unmatched by other imaging technologies at an individual level.

By revolutionizing early-stage disease characterization, QUTE-CE MRI significantly advances both clinical care and biomedical research, improving health outcomes through innovation.

Please provide appropriate references (PubMed, Abstract, Website):

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