**Describe the problem you solve: Position of the problem, novel approach, achievements to date**

Studies indicate that people with PTSD have increased amygdala activity in response to arousing stimuli, as well as reduced activity in parts of the frontal lobe that are responsible for regulating emotional responses. The limbic network, which includes the amygdala, mediates the emotional processing in the brain and plays a key role in many mental disorders. Until Prism for PTSD, no drug, medical device, or behavioral treatment neither directly targeted amygdala hyperactivity and limbic dysregulation nor utilized knowledge of underlying mechanisms of brain activity.

Many pharmacotherapies result in adverse side effects, while psychotherapy – including prolonged exposure therapy, eye movement desensitization and reprocessing and trauma-focused cognitive behavioral therapy - can be particularly challenging as patients are required to relive their traumatic experiences. Additionally, patients living with PTSD can face [stigma, prejudice and discrimination](https://www.psychiatry.org/patients-families/stigma-and-discrimination), which can deter them from seeking talk therapy treatment. As a result of the above, as many as 50 percent of patients prefer to avoid therapy, only exacerbating their medical condition.

Before Prism for PTSD, EEG and fMRI which offer two very different measurements of real-time brain activity, held promise but were ultimately too expensive and cumbersome to operate, and were never combined to produce a therapeutic tool. Prism uses advanced statistical models to convert an EEG signal measured in real time to an amygdala derived EFP biomarker. Through this, Prism remains accessible, affordable, portable and scalable.

Bringing a third option to patients alongside psychotherapy and pharmacotherapy, *Prism for PTSD* is ushering in a new treatment modality for PTSD, and later on for additional mental disorders. Using biomarkers generated by fusing EEG and amygdala-fMRI data, named EFP (EEG-fMRI-Pattern), *Prism for PTSD* takes neurofeedback to the next level, with studies demonstrating its ability to improve overall treatment efficacy, with no severe side effects. It has also shown a high level of acceptance by patients with low attrition.

With the shortage of mental healthcare professionals and remaining professionals in the field overworked and facing burnout, Prism alleviates some of the burden and allows clinicians to enhance clinical outcomes. As an automated solution, Prism not only reduces sole reliance on mental healthcare professionals’ valuable time, but does so as an adjunct treatment, thereby augmenting existing treatment outcomes.

On the clinical front, the results of the clinical study submitted to the FDA mark a significant achievement as they show significant and clinically robust change, even three months after the conclusion of treatment, as well as a high safety profile. The PIs of the study are therefore now considering how to integrate Prism into the clinic workflow on a commercial basis.

In the three years since raising seed funding, the company has received multiple awards including the SelectUSA Investor Summit Medtech Award run by the US Department of Commerce, NYC HITLAB Innovation Award, and GMH is also one of only eight companies worldwide to have received the Nature magazine Spinoff Prize in 2021.

GMH has also forged strong collaborative relationships and partnerships with leading international luminary sites including NYU Langone, McLean Hospital (Harvard University’s largest psychiatric hospital, ranked the best hospital for psychiatry in the USA for the last four years), Charite Berlin, Sheba Medical Center, and more. Of note, Mclean, Charite and Sheba hospitals have all been ranked among the top hospitals in the world by Newsweek and Statista for the last five years.

The company underwent a rigorous due diligence process by Otsuka Japan, who not only invested in the company but also licensed the right of distribution in Japan. GMH, together with McLean Hospital, received grants from the BIRD Foundation who gave a $1,000,000 grant for conducting a depression study. The company has also received a grant from the Israeli Innovation Authority and the EU has also presented a €2, 500,000 grant through the EIC Accelerator as well as invested in the company alongside multiple other experienced investors and VCs.

The most significant achievement to date is the product’s FDA 510(k) clearance granted in March 2023, three years after raising the seed investment and following the completion of the FDA study during COVID-19. GMH has started selling Prism for PTSD to a select number of outpatient and private mental health clinics in the USA. It will expand its sales in early 2024. The company also has plans to expand its clinical development to evaluate how the technology can be applied to treat additional mental disorders.

**Target Market Characteristics**

**What are your targeted markets and their size? Describe other relevant attributes: growth, strengths, weaknesses, trends, disruptions. Who are your competitors on the market?**

There are approximately 250 million people worldwide with PTSD, nine million living in the US and 11 million in Europe. In recent years there has been an uptick in public and private organizations raising awareness for PTSD and the stigma due to an increase in sexual assault, road accidents and most recently, Covid-19. However, the PTSD treatment options have not changed.

GMH’s initial focus is on the US market. This will later be followed by Israel and the EU, starting with Germany, where a 120-patient, five site, two arm study is underway. Other countries in the EU are to follow, as well as Japan where a study will commence later this year. GMH has also initiated discussions with international organizations to later make Prism available in Emerging Markets, most likely starting with Africa.

As we see the patient population grow, we expect to see market growth in kind. However, given the high efficacy, non-pharmacological, low side effect, and self-agency nature of the treatment, we expect Prism treatment could lead to medium-term market growth as 50 percent of PTSD patients who currently refrain from seeking help will be interested in trying the new modality.

TARGETED CLINIC MARKET

Following its recent FDA clearance, GMH has started selling Prism to select outpatient and private clinics. Beyond this, its initial target customers are mental health clinics, both as private practices and within IDNs/HMOs/MCOs, who will offer the service to the population living with PTSD. These clinics experience limited capacity and low therapeutic efficacy driven by available modalities.

There is a shortage of mental healthcare professionals, especially psychiatrists (MDs), leaving professionals in the field overworked and facing burnout. Prism can be operated by a non-MD professional, relieving psychiatric workload, thereby making the treatment more accessible and enhancing clinical outcomes without the need for physician or MD time. Through this, clinicians can reduce the time required in direct interactions with patients, increase their availability to new patients and open access to new patients.

The company plans to offer a pay-per-use model to the smaller private/outpatient clinics and a capitated Per Member per Month (PMPM) model for the larger IDN/HMO/MCO clinics. The company will launch the product in areas with higher private pay, out of pocket, and VA populations (TriCate and VA), as their health insurance plans are more likely to cover Prism therapy. GMH plans to actively engage with payers to form policies around premium coverage, based on existing codes initially, and issuing Level III and Level I code in the long term. In addition, GMH believes that Prism’s digital nature and its positive influence on empowering the individual will be very attractive to millennial populations in major metropolitan areas where higher decile clinics and populations reside.

COMPETITORS IN THE MARKET

Prism is classified in the same category as biofeedback which includes a single breathing-based biofeedback device indicated for PTSD and multiple EEG based neurofeedback devices indicated only for relaxation but not for specific disorders.

In principle, existing neurofeedback companies cannot and do not claim to target a specific dysfunctional process in the brain. Rather, their main claim is training people to alter a set of brain EEG frequency bands to what is considered normal and relaxing. Since no significant clinical trials have been conducted with EEG-based neurofeedback, the technique has not been adopted as a treatment by psychiatric care professionals. Furthermore, the traditional practice of neurofeedback relies heavily on the therapist’s ability to tune and adjust the therapy in real-time. This means that with traditional neurofeedback, unlike Prism, the therapist has to be immersed in the treatment, increasing costs and limiting access.

The breathing-based biofeedback device, while attractive since it allows home use, has faced challenges with prescriptions and compliance. This is due to the value chain circumvents the clinician and relies on the patient to properly use the device at home. Transcranial Magnetic Stimulation (TMS) devices have not been cleared for PTSD, and when used for other indications require a longer regimen cycle and heavier side effects.

GMH is fully positioned to fit this unmet need and interest. With GMH’s technology, these shortcomings of competitive solutions will be addressed, supporting Prism’s introduction as a standard of care – for PTSD and in time, other mental and neuropsychiatric disorders. Based on the company’s industry research conducted with mental healthcare professionals and payors, it appears that mental health therapists are interested in integrating new modalities and are familiar with neurofeedback but are holding back until an FDA cleared device is marketed. Furthermore, existing codes and OOP models allow for a market beach head, to be later expanded with additional future codes.

**Value Proposition**

**What is your solution/program name?** Prism for PTSD

**Describe your solution and highlight its performance/benefits/Describe preclinical & clinical aspects of the product**

During each session, a mental healthcare professional places an EEG cap on the patient’s head, which monitors their brain activity in real time, and begins the Prism audio/visual session. The patient sits in front of a screen showing a virtual scene of a reception room, where the avatars huddle around a reception desk and shout. The patient is then instructed to find a mental strategy, such as memory, emotion, or experience, that would make the avatars sit down. The avatars will sit down once the patient finds the mental strategy that lowers the amygdala-derived-EFP biomarker signal that is computed in real time using the EEG input. This method is known as neurofeedback, performed on the amygdala-derived EFP.

As the patient practices different mental strategies, Prism for PTSD calculates the amygdala-derived-EFP using the EEG signal and changes what is happening in the virtual scenario (i.e. reception room). As patients find a strategy that lowers the signal, the reception room quietens. Over the course of 15 sessions, patients hone their strategy and improve with time. Providers can then prescribe additional booster sessions to reinforce the effect after the initial regimen.

In a treatment journey that is often stigmatized, Prism for PTSD personalizes therapy. Each patient comes up with their own strategy for lowering the biomarker, whether a happy memory or counting to ten. Crucially, Prism for PTSD does not focus on trauma and patients do not need to relive their experiences, which helps drive the product’s low attrition rates.

In the multi-center clinical trial study, Prism for PTSD displayed a high clinical efficacy with a close to 70 percent response rate and over 30 percent remission, even three months after the conclusion of treatment. Prism also demonstrated a low rate of adverse events, and a low attrition rate with patients experiencing few side effects during treatment.

Clinic integration is also easy, taking two to three hours and Prism was built with the clinic workflow in consideration. This leads to low adoption barriers, low operating expenses, and addresses access restrictions to mental healthcare. Ultimately, Prism can serve both patients and clinics clinically and economically.

**What is your competitive edge? How does your solution compare to competition (including existing solutions and those being developed)**

Prism for PTSD is the only FDA cleared, non-invasive, accessible, and efficacious therapy focused on specific brain regions associated with PTSD, with little to no side effects. Offering a new, third, modality augmenting pharmaco- and psychotherapy, Prism is a unique solution in the industry.

Prism is a neurofeedback device, classified in the same category as biofeedback. While other neurofeedback devices exist, none have FDA-approvals for specific indications. Many of these companies and devices cannot target specific dysfunctional processes in the brain, rather training patients to alter a set of brain EEG frequency bands to a state of normalcy and calm. Since no significant clinical trials have been conducted with EEG-based neurofeedback many mental healthcare professionals have not adopted the treatment. Unlike Prism, these neurofeedback treatments are reliant on the therapist adjusting the therapy in real-time, requiring physicians to be present during the treatment, increasing costs and driving existing accessibility challenges.

Another company has introduced breathing-based biofeedback devices. These treatments are attractive to patients due to their use at home, however, the value chain circumvents the clinician and relies on the patient to properly use the device at home, driving issues with prescriptions and compliance. In addition, Transcranial Magnetic Stimulation (TMS) devices have not been cleared for PTSD, and when used for other indications require a longer regimen cycle and induce heavier side effects.

**Business Model: What will be your marketing and sales strategy (prospection, distribution channels, etc.)? How do you acquire customers? What does a typical sales cycle look like?**

Unlike digital therapeutic companies, GMH’s business model and go-to-market strategy is based on existing marketing models and will use reimbursements codes and billings to ensure a simpler integration into the existing health system.

GMH is following a modified xP-marketing model. The go-to-market strategy is based on phases where each phase builds the assets needed for the next phase. The first phase is the soft launch where GMH will be selling and installing the device in ten select sites, representing different segments of the market. The objective is to demonstrate product robustness, per clinic patient ramp up and success using Prism, and validate the pre- and post-sale processes including training, customer support, utilization, and billing. Treatment will be administered by mental healthcare professionals in outpatient clinics in two categories:

1. Small private mental healthcare clinics, which are typically a group-practice employing several mental healthcare professionals of varied training, with up to five such professionals. GMH regards these as providing short term growth and real-world evidence that may assist us in establishing long-term credibility and experience.
2. Large out-patient clinics of mental health or GP institutions such as an IDN, MCO, or HMO, which typically has a network of facilities each with an out-patient clinic, or a larger private clinic. In such clinics, decision making is a lengthier process, typically involving a pilot phase. GMH regards these institutions as providing longer-term growth and scale.

With a primarily SaaS (Software as a Service) model, GMH plans to sell Prism for $9,000 (at cost), and a list price charge of $50-60 per session as an operating fee. Based on interviews conducted with payers and HCPs, GMH was able to validate that current neurofeedback codes (90875-76) payment averages at $120/session. Furthermore, HCPs believe they can charge $200-300 per Prism session in private settings for clinics not working with payers (about 44 percent). This price point was well accepted in early discussions with payers as well. These codes will be supplemented by a series of E&M codes.

GrayMatters Health’s business model takes into account the above reimbursement payments for the clinic. The clinic will then pay GMH the $350-60 per session fee (list price) out of the per session reimbursement it charges. On average, the Prism model yields an ROI of four months for the clinic with only 25 percent utilization (two sessions per day) an addition of $88,000 to the clinic’s business. This ROI means fast transition into profitability. With a 50 percent utilization (or $176,000 per year), ROI time drops to two months.

Larger out-patient clinics and organizations (HMOS, MCOs, IDNs) will typically employ at Per Member Per Month (PMPM) model. In this model GMH will be paid monthly or annually per the number of members who have been prescribed with Prism therapy. The advantage of this model is in reduced revenue variability, the disadvantage is longer set-up time.

GMH will market its product through a number of avenues including:

* Papers and publications of studies in peer reviewed magazines
* Speaking and presenting at conferences and exhibits.
* Reference sites – Mclean Hospital will serve as a reference site
* Testimonials from Prism for PTSD patients
* Collaborations with leading institutions in the USA
* Promotions from patient advocacy and professional such as APAs, SAMSHA, NAMI, and others