Click Therapeutics

Prix Galien Awards

Category: Best Startup

General Information

Company Name: Click Therapeutics

Product/Solution Name: Prescription Digital Therapeutics

Date of Approval (If FDA approved): n/a

Sub-Categories: Digital Health

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The Problem: Access and Effectiveness

Sophisticated treatments have been developed for some of today's most prevalent health conditions, and yet, significant gaps remain among complex, multifaceted and uniquely individual conditions.

Migraine, for example, is a debilitating and burdensome disease, causing pain, disability, nausea and incapacity for hours to days. It is the third most prevalent illness in the world, affecting 1 billion people worldwide. The World Health Organization has ranked migraine among top 20 most disabling diseases. Prescription and non-prescription pharmacologics are available for temporary relief, but rarely result in full remission from migraine, leaving a clinically significant unmet need of remaining monthly migraine days for many patients. In terms of preventing migraine from the outset, a study involving over 160,000 participants found that only 12.4% said they used preventative treatments (Diamond et al., 2007). Starting a preventive treatment for migraine may be the first time a patient may have had to acknowledge having a serious illness, while for others, side effects, cost, access or insurance status may be limiting factors.

This high burden and high unmet need in conditions like migraine spurred Click's interest in developing safe and effective prescription digital therapeutics that can target the underlying neurological components of disease.

Our Novel Approach: Engaging and Adaptive Prescription Digital Therapeutics

Click Therapeutics moves beyond the digitization of cognitive behavioral therapy. Our cross-functional team uses strong clinical foundations to shape entirely new treatment experiences rooted in evidence-based practices while leveraging the power of technology to deliver treatment in the most efficacious and engaging manner.

Click's approach involves leveraging its proprietary cognitive and neurobehavioral platform to develop Digital Neuroactivation and Modulation (DiNaMo™) interventions that target specific areas of the brain to improve cognitive function and behavioral outcomes through structured audiovisual, haptic and cognitive stimuli. DiNaMos aim to target or correct specific neural pathways that are faulty or underlie the etiology of multiple diseases or indications. These are the building blocks of innovative new PDTs, enabling us to create targeted treatments that are transdiagnostic, offering opportunities to target multiple indications.

Click Therapeutics is the first company ever to achieve a drug-like endpoint with an app and validate it via fMRI through the use of our proprietary DiNaMo, the Emotional Faces Memory Task (EFMT). This novel intervention, EFMT, targets and ameliorates specific neural network abnormalities observed in MDD. It works by targeting imbalance between the hyperactive emotion processing regions and the hypoactive prefrontal regions underlying the cognitive control impairments observed in MDD patients. We observed 45% reduction in HAM-D versus 25% in the control group in two peer-reviewed randomized controlled trials, with objective fMRI data supporting our hypothesis that EFMT has a neuroplastic effect.

In addition to pioneering novel DiNaMos, Click is a leader in digitizing widely accepted evidence-based treatment mechanisms by optimizing these interventions for the smartphone, while maintaining critical clinically efficacious elements. These Translational MOAs are intended to work synergistically with DiNaMos to create robust treatment effects. Oftentimes these aspects of treatment are increasingly difficult for patients to access via traditional clinical care due to national provider shortages, etc., particularly in the case of highly specialized care. For example, Click's preventive migraine treatment employs, among other techniques, cognitive and behavioral therapies, grounded in the scientific principles of face-to-face treatment (Bae et al., 2021) and behavior modification, risk-factor optimization, and medication management and adherence (Lee et al.,2019, Minen et al., 2016; Minen et al., 2019, Penzien et al., 2015).

Digital tools, such as just-in-time delivery of interventions, enable our platform to personalize a patient's treatment journey. After capturing patient inputs such as treatment start timing, app usage and treatment adherence, the platform will analyze the relevant data to send the right message to the user at the right time, varying in tone, content and engagement tactics. Analyzing how patients respond to

these messages through app opens, treatment adherence and performance, allows us to incorporate learnings into the platform to promote a better patient experience and higher engagement across all our products. When viewed across three of our studies, we have found that patients spend an average of 87 weekly minutes in the treatment app and stick to their treatment, resulting in a 75% average daily treatment retention.

The ability to iteratively improve therapies is a key feature of prescription digital therapeutics, making Click products impossible to genericize or replicate. This 'moving target' is an important aspect of our platform approach, as we continue to apply learnings to our products and make it more difficult for any company that seeks to replicate our approach.

In the example of migraine, software-based therapeutics can leverage advanced algorithms and data analytics to analyze individual patient data, such as migraine symptoms and medical history to deliver tailored migraine treatments. This customization allows for targeted CT-132 interventions that address specific needs and variations in patient responses.

Treatment can be accessed remotely, enabling patients to receive treatment without the need for in-person visits or frequent trips to healthcare facilities. The integration of behavioral support with medication can enhance treatment outcomes and empower patients to actively participate in their own care. Our extremely positive quantitative (retention) and qualitative (user interview) data validates our approach.

Achievements:

In 2022, Click broadened and accelerated its digital therapeutic R&D programs, supporting initiation or completion of 10 clinical trials across 9 therapeutic areas including neurology, oncology, inflammatory disease and serious mental illness. In sum, Click has enrolled more than 1,000 patients in early and late-stage studies. Click's R&D efforts represent a continued commitment to building prescription digital therapeutics that integrate clinical science with patient-centric design to build efficacious and engaging treatments in therapeutic areas with high unmet need, combined with the rigors of traditional therapeutic development. Highlights from the year include:

DiNaMo R&D Program

We launched Click's Digital Neuro-activation and Modulation (DiNaMoTM) neurobehavioral intervention research and development program to enable new therapeutic areas. Click's DiNaMo R&D program develops and evaluates digital mechanisms of action targeted to one or more neural pathways implicated in disease expression. The DiNaMo program was conceptualized, developed and validated at Click by a multidisciplinary team with backgrounds in neuroscience, serious gaming, medicine and mobile application development.

Click completed enrollment and study assessments for two randomized, controlled, fully decentralized DiNaMo studies in 2022. The first was a basket study evaluating the impact of a cognitive intervention

on gold-standard objective outcomes in participants with multiple sclerosis or breast or lung cancer, indications that share cognitive dysfunction as a factor of disease progression or treatment. Clinically meaningful changes in outcomes of interest have been observed in each indication, supporting opportunities for further development within these therapeutic areas.

The second basket study evaluated an attention modification task in conditions that share chronic pain as a transdiagnostic feature including diabetic neuropathy, irritable bowel syndrome, fibromyalgia and rheumatoid arthritis. The protocol for this study was presented at CNS Summit in November 2022. The study recently completed enrollment in December with data analysis now underway.

Implementation of advanced in-house clinical operations capabilities

Central to the design and validation of Click's digital therapeutics treatments are the company's clinical operations, including both hybrid and fully decentralized approaches to study capabilities. Using validated tools and multi-channel engagement strategies for all stages of research reduces study costs, resource needs and time to execute. Our decentralized trials meet the participant on their schedule and on their terms to garner trial data reflective of how people live while seeking treatment. As a measure of success of these operational capabilities, Click saw enrollment completed in an average of 2.3 months for Click managed studies.

Ongoing development of digital therapeutics to treat serious mental illness

Click continues to advance studies in schizophrenia (CT-155) and major depressive disorder (CT-152) in partnership with Boehringer Ingelheim and Otsuka. In 2023, Click initiated a FPI for a phase 3 randomized trial for CT-155.

Results from Click and Boehringer Ingelheim's first clinical learning study were presented at Psych Congress and Neuroscience Education Institute in 2022. In 2023, We presented data from our second clinical learning study at some of the leading congresses in psychiatry (APA, SIRS, ASCP).

As recently announced, this and other supportive data across additional clinical learning studies have contributed to the expansion of Click's partnership with Boehringer Ingelheim to include development of an additional digital therapeutic.

Progress in developing a digital therapeutic for Migraine (CT-132)

The migraine program recently received Breakthrough Device Designation (BTDD) from the U.S. Food and Drug Administration that will enable expedited development and review. BTDD submission was supported by a series of studies that demonstrated robust patient engagement with precursor versions of the digital therapeutic. The first study leveraged smartphone-based ecological momentary assessment and passive data sensing to establish the framework for study app data and biometric parameter collection.

The second study evaluated the impact of an abbreviated version of the digital therapeutic on establishment of a Digital Working Alliance (DWA) and exploratory measures of clinical efficacy. The outcomes of this study support the probability of clinical success for CT-132 and were instrumental in achieving BTDD designation. These study results were presented at leading congresses in migraine (AAN, AHS).

Click expects to share the full results of these studies following completion of additional clinical trials in the migraine program, including the pivotal registration study utilizing gold-standard endpoints common in pharmaceutical registration studies. This pivotal study initiated FPI earlier this year and is one of the largest remote clinical trials for a digital intervention in migraine to date.

Expansion of Click's intellectual property portfolio

In 2022 and the first half of 2023, Click grew its intellectual property (IP) portfolio with 14 granted patents and 40 patent applications worldwide, further strengthening the company's growing IP assets. These efforts demonstrate Click's commitment to quality innovation and will expedite the commercial importance of its proprietary, cutting-edge technologies and inventions. In the remainder of the year, Click looks forward to continuing to build its IP position with a number of new patents currently in preparation.

Partnering with strategic organizations to enable digital therapeutic adoption

Earlier in the year, Click partnered with Altoida to support clinical research leveraging their augmented-reality technology to assess brain health across Click's pipeline, accelerating insights into individual's patterns of disease. Furthering the mission to expand access to high-quality care, Click partnered with The Massachusetts Medical Society (MMS). Founded in 1781, the MMS is the statewide professional association for physicians and medical students with over 25,000 members and publisher of the New England Journal of Medicine. This collaboration aims to advance the practice of medicine, whereby Click sponsors the MMS Information Technology in Medicine Award and advances discussions with MMS committee members on PDT education and access to new modalities of therapy.

DESCRIBE YOUR 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? (< 1000 words)

Click Therapeutics is primarily targeting markets in the US, the EU, the UK and Japan, though our vision is global. Our product pipeline addresses a wide range of therapeutic areas, from central nervous system-related therapy areas focused on serious mental illness, to cardiometabolic disease and oncology. Each of these areas has significant numbers of underserved patients who would benefit from new treatment options.

With the rise of smartphone adoption globally (85% adoption in the U.S.), there is an opportunity for innovators to utilize this new technology to deliver positive health outcomes especially for those

patients in health deserts where quality healthcare is not accessible. For example, in one of our therapeutic areas of focus, migraine, patients routinely face challenges in getting access to treatment. With only 700 headache specialists in the country, many patients have to wait several months to receive their initial diagnosis and treatment plan, and additional months to get a follow-up check up if their prescribed treatment is not adequate. The ubiquity of smartphones helps bridge the gap of care and allows us to potentially make an impact for all patients who have access to a smartphone.

The increased focus to tackle mental health issues have garnered support from the federal government to enable new technologies solving for this national crisis. According to the CDC, in 2021, two in five American adults reported experiencing symptoms of anxiety and depression and forty-four percent of high school students reported struggling with persistent feelings of sadness or hopelessness exacerbated by the COVID-19 pandemic, social media and gun violence (National Center for Health Statistics, 2020-2023). With the Biden-Harris Administration firmly committed to addressing this crisis, there is a recurrence of support to enable new healthcare technologies. The federal government's support in this endeavor is also evident in the new codes that have been put out by Centers of Medicare & Medicaid services (CMS) to enable more digital modalities for treatment. In 2022, CMS established HCPCS code for physicians to bill for prescription digital behavioral therapy. Lastly, on March 2023 U.S. Senators Jeanne Shaheen (D-NH) and Shelley Moore Capito (R-WV) and U.S. Representatives Kevin Hern (OK-01) and Mike Thompson (CA-04) reintroduced bipartisan, bicameral legislation to increase access to Prescription Digital Therapeutics (PDTs). This bill will expand Medicare coverage to include PDTs and will provide guidance to Commercial Payers on how to evaluate, cover and pay for PDTs.

However, challenges to drive adoption of new technologies in the healthcare industry continue to exist. Despite the lack of side effect profile due to the digital nature of the delivery modality, healthcare professionals, insurers and regulators continue to be wary about adopting PDTs. They have placed additional evidence requirements for PDTs in comparison to traditional pharmaceuticals - and innovators are challenged to meet these requests. With Click Therapeutics' approach to demonstrate change in drug-like endpoints in our multi-study evidence generation efforts, we expect to meet and exceed the standards of evidence requested by the stakeholders. As a PDT industry, there is a collective need to educate healthcare professionals and insurers to increase comfort with the modality and increase confidence in incorporating the products into practice.

With this need for collective effort, we consider other prescription digital therapeutics companies as counterparts working toward the common goal of creating the foundation for this industry. In therapeutic areas where synergistic efforts between traditional pharmaceuticals and digital solutions are needed, PDTs welcome the opportunity to work together to deliver therapeutic value for the patients. However, in therapeutic areas where incumbent pharmaceuticals cannot fully address patients' needs, due to efficacy or side effects, Click considers traditional pharmaceuticals as competitors. With Click's "Patient First" value identity, our goal is to provide patients with a holistic and effective treatment with them in the center. Click encourages others in the industry to adopt a similar approach as they pursue clinically validated treatments that improve patient outcomes.

Click Therapeutics

WHAT IS YOUR VALUE PROPOSITION?

What is your solution / program name?

Prescription Digital Therapeutics

Please describe your solution and highlight its performance/benefits.

We apply scientific rigor to prescription digital therapeutics.

Click uses biotech-like capabilities and methods to apply an unprecedented level of scientific rigor to PDT innovation, which is critical for these therapies to be considered viable treatment options. Click's digital therapeutics are subject to FDA clearance, addressing symptoms with drug-like efficacy and improving outcomes for patients with serious illnesses.

Click's industry-leading platform targets the brain's neural pathways that underlie the etiology of multiple diseases. Drugs either up- or down-regulate the brain, but digital MoAs target and correct individual brain circuits. By targeting multiple domains within each indication—sensory, attention, cognition, neuroanatomy, neurophysiology, executive functioning and more—we can provide novel and holistic treatments. Deliberate and consistent use of our therapeutics establish new neural connections and activity for durable and lasting results. Through neurophysiological studies, we can show how each regimen can be further customized to suit the goals of the individual to maximize engagement and support cumulative progress.

Click's evidence-based mobile applications are safe and engaging.

Prescription medications can have a wide range of potential side effects and toxicities, which can vary depending on the individual's response to specific medications. Medications can also interact with other drugs or substances, potentially leading to adverse reactions.

Prescription digital therapeutics, on the other hand, have a higher safety profile due to their digital nature, over-the-air delivery, no anticipated drug-drug interaction, and no expected systemic toxicity. Digital therapeutics typically do not involve the use of chemical substances, and therefore they do not have the same potential for toxicological effects or side effects as prescription medications. However, at Click, in all our clinical trials, whether Pivotal or Pilot Clinical Trials, we follow subjects' safety very closely under FDA's advice and report all adverse events following Good Clinical Research Practice (GCP) and FDA's well established safety guidelines.

Additionally, Click's mobile-first approach delivers clinical value upfront to patients via a carefully curated set of therapeutic activities that flux depending on a patient's current place in their journey. We use game and consumer product development principles, such as rich media and narrative design to craft more engaging content that helps patients stay engaged with treatment and understand the difficult material in a more approachable way.

Click Therapeutics

Our migraine product in particular has engagement features that deliver the therapeutic guidance as if it were a challenge, enabling patients to create meaningful lifestyle changes to reduce their migraines all while receiving treatment. Our exploratory study highlighted that engagement with the respective treatment elements was high. Specifically, participants completed an average of 13.2 daily lessons with recommended therapeutic skill practice (out 14 total possible), accessed the ad hoc migraine attack support an average of 4.5 times, and completed extra therapeutic skills an average of 3.4 times during the 14-day study intervention period. This high rate of engagement indicated the application functioned as intended and participants were able to follow application instructions, resulting in a completed course of treatment as delivered by the abbreviated version of CT-132.

Our ability to engage patients through this approach enabled us to develop a positive DWA at the conclusion of the 14-day intervention in this exploratory study, signaling that CT-132 effectively delivers treatment elements that establish a bond akin to the critical therapeutic alliance of face- to-face intervention.

Describe Preclinical & Clinical aspects of the product? (< 500 words)

The preclinical phase of a prescription digital therapeutic and a prescribed pharmacological medication share similarities but also have notable differences due to the nature of their respective interventions. Preclinical studies for prescribed medications aim to establish the safety profile of the medication and provide initial insights into its potential therapeutic benefits.

Prescription digital therapeutics, as a relatively newer field, do not have a standardized regulatory framework specifically tailored to preclinical studies. The regulatory landscape for prescription digital therapeutics is evolving, and developers like Click often need to engage with regulatory authorities to determine the appropriate validation methods and safety considerations for their specific digital therapeutic.

Despite these differences, both treatments aim to provide critical evidence of safety, efficacy and feasibility before proceeding to clinical trials. For prescription digital therapeutics, preclinical studies may involve similar safety assessments, especially if the software interacts directly with hardware components or uses sensors. Preclinical studies for prescription digital therapeutics often involve computational modeling and simulation studies to evaluate the therapeutic potential of the software and its ability to achieve the desired outcomes. However, the emphasis is more on validating the software's functionality, usability and accuracy in delivering the intended therapeutic effects. This may involve testing the software on simulated patient scenarios or using digital surrogates for in vivo or in vitro models.

Our migraine product, for example, is a mobile smartphone application designed to offer an interactive software-based intervention for preventing episodic migraines in late adolescents and adults aged 18 years or older. This innovative intervention serves as an adjunctive treatment alongside standard

pharmacotherapy. The program spans a duration of 12 weeks and incorporates well-established cognitive and behavioral therapies that have been widely accepted in clinical practice. The selection of therapeutic techniques is based on clinical evidence, and the individual components have been developed with the core principles of face-to-face treatment in mind. These types of interventions have demonstrated efficacy in preventing migraines and encompass strategies such as behavior modification, optimization of migraine attack risk factors, and effective management and adherence to medications (Minen et al., 2016; Minen et al., 2019). Our migraine product delivers treatment through daily lessons, fostering engagement and introducing patients to therapeutic content and skills. As the treatment progresses, the lessons reinforce the practice of previously acquired skills and behaviors. The lessons follow a progressive structure and are organized into modules based on therapeutic goals.

In this Pivotal Phase 3, randomized, double-blind ReMMi-D (Reduction in Monthly Migraine Days) trial *(ClinicalTrials.gov Identifier: NCT05853900),* Click is enrolling approximately 558 patients in the United States. Efficacy will be evaluated between groups as a change from baseline in the number of monthly migraine days (MMDs). A successful intervention would lead to a statistically significant reduction of MMDs, a robust and clinically relevant indicator of treatment efficacy, experienced by patients, demonstrating the therapeutic impact and potential preventive benefits of the treatment. This endpoint provides meaningful evidence for the treatment's ability to reduce migraine occurrence and possibly decrease the need for acute migraine medications.

What is your competitive edge? How does your solution compare to competition (existing solutions on the market or solutions being developed by competitors)? (250 words)

We put the power to heal in the palm of a patient's hand.

We deliver carefully curated therapies that adapt to a patient's current state in an engaging and approachable way. Our digital therapeutics are high-quality, mobile first, and developed with the patient in mind at every step of the process.

We take a biotech-like approach to R&D, ensuring our products are put through drug-like clinical validation.

While other digital therapeutics focus on wellbeing, Click develops PDTs to be prescribed by HCPs and regulated by regulatory agencies. With a biotech level of rigor and focus on proven safety and efficacy, we can achieve drug-like outcomes that build trust with providers and patients. We are creating novel approaches to treat disease; Click is the first company with a digital intervention that achieved a drug endpoint, demonstrated evidence of its neuromodulatory mechanism of action via fMRI, and then integrated it into a comprehensive and engaging PDT.

We develop innovative therapies that encourage modulation of impaired neural pathways, modifying the course of disease.

This neuroplastic effect is achieved by engaging the patient in emotional, cognitive, behavioral or physical activities engineered to alter the underlying mechanism of their condition. These therapies deliver benefits without side effects typical of pharmacological approaches, creating value for pharma partners who partner with us, providers, patients, and the larger healthcare system. As a result, we have two industry-leading partnerships with pharma with the largest monetary value based on publicly available information.

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? (500 words)

Marketing and Sales Strategy

Click Therapeutics takes both a nationally and regionally focused approach when it comes to our marketing and sales strategy. We recognize the importance of access and the existing challenges that surround it. It is our priority to ensure that we are enabling the healthcare system to deliver the right treatment to the right patient at the right time. Given the prescription nature of Click's treatment solutions, we identify payers, providers, and patients as our key customers. Our internal strategy is designed to ensure that all stakeholders understand the value of PDTs and believe in their therapeutic and economic value proposition. The goal is for patients to actively engage with our products, providers to write prescriptions for our products, and payers to provide favorable coverage and access to our products.

Building awareness and education around what PDTs are and the value they bring is key to initiating product-specific conversations with the stakeholders. At Click Therapeutics, we tackle unbranded market shaping in two ways. First, we use thought leadership opportunities to build awareness and education for the PDT industry through speaking engagements and through key conferences with industry audiences. Second, our existing collaboration with pharmaceutical partners allows us to shape the market through their existing network of MSLs, policy lobbyists and Payer account managers to increase awareness and educate the market.

Engaging with payers early to discuss evidence packages and address access challenges ensures that access and distribution of our treatments is not an issue. Additionally, we want to ensure that healthcare providers (HCPs) have the information they need to be able to make informed clinical decisions for their patients. We aim to instill data-driven confidence in HCPs and ensure they feel supported before they make a clinical decision to prescribe our products. Click's Chief Medical Officer Shaheen Lakhan, MD, PHD, often works directly with medical schools, societies and associations to integrate prescription digital therapeutics into the curriculum and establish foundational scientific knowledge on PDTs to support the next generation of providers.

Once the market is primed for PDTs, we plan to take a traditional pharma digital omnichannel marketing approach to reach patients and providers, and utilize targeted traditional sales force models to reach

and educate providers on our products. In order to gain insurance coverage for our products, we plan to employ a team of account managers and payer marketers to deliver our clinical and economic value story, and drive access and coverage for our products prior to launch.

Sales Cycle:

Because our products go through traditional pharmaceutical access channels, the contracts are typically considered and evaluated in an annual calendar year. With a robust pre-launch evidence package and early payer engagement activities such as Pre-approval Information Exchange (PIE), we aim to facilitate early account team discussions with Payers to ensure access is available at launch.

If target Payers prefer pilots and VBCs prior to standardized coverage, we plan to facilitate discussions on structuring and executing Payer/IDN pilots prior to commercial launch.

FINANCIAL

What will be your operational costs? Your expected revenue? How will the project be financed (Self-financing, Investors, etc.)? What are the capital requirements? What are the potential risks you may encounter and your contingency plan to address these risks (regulatory, financial, economic, technical, scientific, etc.)? What will be your needs & costs in term of regulation (FDA accreditation, reimbursement, etc.)? (< 2000 words)

In 2023, Click Therapeutics expects to accrue over $50 million in revenue. We are investor backed, with H.I.G. BioHealth Partners and Accelmed Partners co-leading our last financing round, and are fully capitalized.

Our products are intended to be cleared by the Medical Device center of the FDA and backed by rigorous clinical studies demonstrating both favorable safety and efficacy. As a result, Click's success is contingent on our ability to generate positive clinical data to support claims that we provide clinically meaningful benefits to patients.

Click's business model is supported by significant and enduring partnerships with pharmaceutical companies that are unmatched in the prescription digital therapeutics space.

Terms for our partnership with Otsuka, for example, include funding such as: $10MM for Upfront & Regulatory Milestone, $272M for Commercial Milestone Payments and $20MM for Development Funding $20MM. Royalties have a tiered, double digit structure.

Our initial collaboration with BI, announced in September 2020, has a financial structure that includes $500MM + tiered royalties. Two years later, the partnership was expanded to develop and commercialize another prescription digital therapeutic for schizophrenia. That collaboration includes $460MM + tiered royalties.

TEAM AND SUPPORT

Click Therapeutics

Please present the dedicated team to the project; Do you have an advisory board? If yes, please describe the members; Does your project have social impacts (job creation, development of new skills and qualification, etc.)? (&60; 1000 words)

Scientific Advisory Board

Andrea Leonard-Segal, M.D., F.A.C.R. - Former Division Director, FDA; Clinical Associate Professor of Rheumatology, George Washington School of Medicine

Joe Kvedar, M.D. - Editor-in-Chief, npj Digital Medicine; VP of Connected Health, Mass General Brigham; Professor of Dermatology, Harvard Medical School; Co-Chair, Digital Medicine Payment Advisory Group, American Medical Association (AMA)

Stewart Tepper, M.D., F.A.H.S. - Board of Directors, American Migraine Foundation; Professor of Neurology, Dartmouth School of Medicine; Director, Headache Center, Dartmouth-Hitchcock Medical Center; Editor-in-Chief, Headache Currents; Associate Editor, Headache

Nicholas Schork, Ph.D. - Distinguished Professor and Deputy Director of Quantitative Medicine, Translational Genomics Research Institute (TGen); Adjunct Professor at City of Hope, UCSD, Scripps Research

John M. Kane, M.D. - Senior Vice President, Behavioral Health Services, Northwell Health; Chairman of Psychiatry, The Zucker Hillside Hospital ; Former President, American Society of Clinical Psychopharmacology (ASCP); Former President, Schizophrenia International Research Society (SIRS)

Maurizio Fava, M.D. - Psychiatrist-In-Chief, Massachusetts General Hospital; Director of Clinical Research, Mass General Research Institute; Executive Director, MGH General Psychiatry Clinical Trials Network & Institute; Professor of Psychiatry, Harvard Medical School

WHAT IMPACT HAS YOUR PROJECT ON SOCIETY?

Please explain how your project benefits to society (product with societal benefit, impact in terms of public health, quality of life, circular economy, etc.? (250 words)

Access

Accessibility is one of the largest value propositions for prescription digital therapeutics. Our vision is for any patient with a smartphone, located anywhere in the world, to be able to access our high-quality and clinically-validated treatments.

Patient-focused treatment options

The patient is at the core of our business. With the understanding that every patient's treatment journey is different, Click's digital therapeutics are tailored for each individual to ensure that journey is a

successful one, using one of the most personal items patients own—their phone. The products adapt during treatment while simultaneously using learnings to become smarter and more predictive.

Our products also do not produce the side effects commonly associated with existing drugs and devices that require physical interaction. Due to the software-only nature of our products, the anticipated safety profile of our products are advantageous compared to existing approved or cleared treatment alternatives.

Better Outcomes for All

Whether they are not addressed by available therapeutics, under-addressed by the current standard of care, or have limited treatment options, many diseases and behavioral conditions present persistent challenges. We exist because we believe in the power and potential of technology to address them.

Software as medicine presents benefits to both patients and payers - improving quality of life, reducing pain, and limiting the number of days and money lost due to illness or suffering – while supporting the overall healthcare system. Software also presents an opportunity to realize environmental benefits, limiting manufacturing footprints and reducing product waste.

We believe that doing our best to create these solutions means pushing past the boundaries of traditional medicine, working on the next medical frontier, and helping the human body to heal in order to restore health. That is at the heart of why we were founded.

ROADMAP

What are the midterm and long term next steps for the project? (250 words)

In the year ahead, Click will expand our library of validated DiNaMo interventions, run multiple registrational trials and real-world-evidence studies, and further partner with trusted pharmaceutical companies who share in our vision to increase access to best-in-class therapeutics for patients in need. We will also additionally look to expand our pipeline of internally developed PDTs into new indications.

For our migraine product, the midterm next steps will be to complete the ReMMi-D Pivotal trial successfully and submit for FDA marketing authorization. The long-term next step will be to deliver accessible, clinically proven, FDA-regulated and approved CT-132 prescription treatments to the smartphone in the hands of patients with Migraine.

Why do you apply for the Galien Startup Awards? (Check all that apply)

- To obtain recognition and display your solution
- Gain visibility of your product and company
- Find new actors from your landscape
- Develop a competitive edge to penetrate the US market

Click Therapeutics

Please describe your motivations to apply (2 sentences maximum)

Click Therapeutics is applying for a Prix Galien Startup Award to highlight our innovative approach to the development of prescription digital therapeutics. A Prix Galien Award would demonstrate the value of this approach to potential partners, serving as a catalyst to deliver more holistic treatment solutions that benefit both patients and providers.