

# Prescription Digital Therapeutics

**Category:**

Best Startup

**Company Name:**

Click Therapeutics

**Turnover and/or Funding:**

Over \$100 million

**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):**

Founded in 2012, Click Therapeutics is a science-led biotechnology firm developing prescription digital therapeutics (PDTs) and software-enhanced drug therapies. These can work independently or in conjunction with pharmacotherapies to enhance the standard of care and drive better health outcomes.

While conventional pharmacotherapy is critical, patients often face treatment gaps, particularly for conditions influenced by structural and functional brain changes. Though smartphones spurred digital therapeutic development, many lacked scientific rigor and clinical validation. Click believes digital therapeutic developers must deliver prescription treatments offering the quality and rigor expected of new medicines. Click Therapeutics is well-positioned to lead the charge in developing digital therapeutics that build trust with patients, providers, and payers.

Click Therapeutics has introduced many industry firsts, with three devices receiving FDA marketing authorizations. Click's self-developed CT-132, a first-in-class PDT for preventing episodic migraine, was granted De Novo classification by the FDA. In collaboration with Otsuka, Click developed Rejoyn™, the first FDA-authorized prescription digital therapeutic for adjunctive treatment of major depressive disorder symptoms. The company also expanded into cardiometabolic disease with AspyreRx, which received FDA marketing authorization for type 2 diabetes treatment.

Click Therapeutics has also received two Breakthrough Designations from the FDA for migraine (CT-132) and schizophrenia (CT-155) products. Strengthening its oncology pipeline, Click Therapeutics recently announced plans to accelerate development in obesity and cardiometabolic disease through the acquisition of Better Therapeutics, Inc. assets. Click's leaders and developers are excited to adapt AspyreRx to their AI-enabled platform, optimizing it for co-prescription with medications like GLP-1s. These milestones demonstrate how digital therapeutics are positioned to help define the future of clinical care.

To date, Click has raised over \$100 million in total capital from investors who understand the value of rigorous biotech development and testing. Key funding rounds include: Sanofi Ventures and Hikma Ventures (2018); H.I.G. BioHealth Partners and Accelmed (2021, \$52 million Series B); Silicon Valley Bank (2022, \$15 million debt financing); and HSBC Ventures (2023, \$20 million debt financing to refinance SVB loan and fund investments). In March of 2025, Dassault Systèmes announced a strategic investment, providing the entire Series C funding round. This established a strong partnership between Click Therapeutics and Dassault Systèmes' Medidata Solutions, designed to extend the patient experience beyond clinical trials to include digital therapeutics in the real world, enabling enhanced long-term patient benefit and robust real-world data opportunities.

In addition to funding, Click's partnerships with pharmaceutical companies contribute to its financial health and are a key part of its business model. Click has announced four industry-leading co-development and commercialization collaborations with pharmaceutical companies, including Otsuka Pharmaceuticals and Boehringer Ingelheim.

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

In April 2025, Click Therapeutics obtained FDA marketing authorization for CT-132, the first prescription digital therapeutic for the preventive treatment of episodic migraine in adults. This authorization is based on data from the ReMMi-D (NCT05853900) study, where CT-132 met its primary endpoint, showing a significant reduction of approximately 3.0 monthly migraine days from a baseline of 7.8 to 4.5 days after 12 weeks. Almost twice as many participants reported improvement using CT-132 vs. sham. Clinical results from the ReMMiD-C bridging study (NCT06004388), showing similar performance in patients taking CGRP inhibitors, were also submitted.

In 2019, Click announced a worldwide collaboration with Otsuka for CT-152, a PDT for Major Depressive Disorder (MDD), now known as Rejoyn™. Rejoyn, leveraging novel cognitive-emotional brain-training exercises ("Emotional Faces Memory Task"), helps

alter neural connections to process emotions and reduce depression symptoms. Its clearance is based on data from the Mirai study, one of the largest digital therapeutic studies to date, which demonstrated a clinically meaningful benefit beyond existing antidepressant medication.

Click also established a worldwide collaboration with Boehringer Ingelheim in 2020 to develop and commercialize CT-155, a potential first-in-class treatment for the negative symptoms of schizophrenia. The results of a pivotal clinical trial (CONVOKE), which enrolled approximately 432 patients to investigate the use of CT-155 as an adjunct to standard-of-care antipsychotic therapy, will soon be available. CT-155 received Breakthrough Designation from the FDA in 2024. In 2022, the partnership expanded to develop CT-156, a second prescription DTx treatment for schizophrenia.

Click Therapeutics also developed Multimodal Multistable Bias Modification (MMBM™), a novel smartphone-based neuromodulatory intervention for individuals with breast cancer. The MMBM intervention is designed to address changes in brain circuitry linked to cancer- and cancer-related factors, which play a key role in regulating cognitive, emotional, and sensory processes, including how patients perceive pain and are able to regulate cancer-related distress and mood symptoms.

In our randomized, controlled pilot trial (NCT06136923) of 81 breast cancer survivors, those in the treatment arm using the MMBM™ app experienced on average a significant improvement compared to a sham control app in fatigue (improvement of 3.4 points,  $p < 0.05$ ), anxiety (improvement by 3.0 points,  $p < 0.05$ ), and depressive symptoms (improvement of 2.8 points,  $p < 0.05$ ) on the PROMIS-29+2 standardized scale after using the app for just seven minutes a day for four weeks. These differences were also clinically significant, where the change was within the 2-6 point minimal clinically important differences threshold. Only the MMBM app group showed significant improvement across a wide range of pain and pain-related metrics, including pain intensity, pain interference, pain-related distress, and physical functioning (all  $p = 0.05$ ). MMBM intervention produced clinically meaningful improvements in fatigue, mood, and promising signal across pain symptoms in breast cancer survivors.

Earlier this year, Click also acquired assets from Better Therapeutics to accelerate its cardiometabolic pipeline. These efforts demonstrate Click's commitment to quality innovation and will expedite the commercial importance of its proprietary, cutting-edge technologies and inventions.

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

Click Therapeutics develops innovative prescription digital therapeutics and software-enhanced drug therapies to treat disease. Accessible through a smartphone, Click's evidence-based mobile applications are designed to provide safe, effective

treatments by delivering multimodal neurobehavioral mechanisms of action that work independently or in conjunction with pharmacotherapies. Click employs cutting-edge technical capabilities, patient-centric design, and rigorous clinical validation to develop clinically meaningful interventions enhanced by AI and machine learning for adaptive engagement and personalization, all backed by scientific evidence. This approach integrates the best biomedical and technological innovations to expand the possibilities of medicine and place the power to heal in the palm of a patient's hand.

Click's digital therapeutics combine scientifically proven therapies with proprietary neuromodulatory interventions to enable long-lasting, durable change. This new modality of medicine can provide patients with a personalized patient experience, little to no side effects, and improved outcomes. Software is only successful if patients use it, so Click's designers have developed patient-centric applications by incorporating storytelling, user research, and elements of consumer technology. The organization's digital therapeutics are developed on their AI-enabled platform to deliver personalized treatments to patients, which adapt to their pace, symptoms, and responses, increasing engagement and driving superior outcomes.

#### Example In Action

Rejoyn, an FDA-cleared prescription digital therapeutic for major depressive disorder as an adjunct to clinician-managed care, can offer a new and more accessible approach to treatment for those who have an inadequate response to their antidepressant.

Rejoyn is a six-week treatment program designed to help enhance cognitive control of emotion through a combination of clinically validated cognitive-emotional training exercises for the brain and brief therapeutic lessons. Rejoyn, which received FDA clearance based on data from the Mirai study, is currently available to patients in the United States and will soon be available to patients in the United Kingdom. Rejoyn has the potential to help shift the course of mental health treatment by being the first modality of care to introduce the concept of a prescription digital therapeutic for the adjunctive treatment of MDD into the clinical mainstream at scale.

Click Therapeutics also obtained FDA marketing authorization for CT-132, the first prescription digital therapeutic for the preventive treatment of episodic migraine in patients 18 years of age and older. This FDA authorization not only provides clinicians with a new way to treat migraines but also opens the door for the pharmaceutical industry to offer more personalized care and expand the use of prescription digital therapeutics and software-enhanced drug therapies across various conditions.

Digital interventions like MMBM for patients with breast cancer go beyond traditional app-based support, uniquely addressing factors like fatigue, mood, and pain, which are key drivers of a patient's overall quality of life.

While our promising research began with breast cancer, the MMBM app is designed to address fundamental changes in brain circuitry impacting quality of life domains across

many cancer types. This highlights the transformative potential of digital therapeutics and software-enhanced drug™ treatments to directly address the debilitating neurological and psychological symptoms that patients too often face alone.

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

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