SECURITIES & EXCHANGE COMMISSION EDGAR FILING

DTHERA SCIENCES

Form: 8-K

Date Filed: 2018-08-23

Corporate Issuer CIK: 1586372

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **August 23, 2018**

DTHERA SCIENCES
(Exact Name of Registrant as Specified in Charter)

Nevada	**333-191175**	**90-0925768**
(State or Other Jurisdiction of Incorporation)	Commission File Number	(IRS Employer Identification No.)

7310 Miramar Rd Suite 350., San Diego, CA	**92126**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 215-6360**

_____
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☒ Emerging growth company

☐ If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.
Item 8.01 Other Events.

Press Release – FDA Grants Breakthrough Device Designation to DTHR-ALZ

Dthera Sciences, a Nevada corporation (the "Company"), announced on August 23, 2018, that the U.S. Food and Drug Administration (the "FDA") has granted Breakthrough Device designation to the Company's development-stage product, DTHR-ALZ.

Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with medical device developers to expedite regulatory review in order to give patients more timely access to a Breakthrough Device. A "Breakthrough Device" is a device that may be more effective at treating or diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care. Additional information is included in the release.

The Company's press release included as Exhibit 99.1 will be deemed to be "furnished" rather than "filed," pursuant to the rules of the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 23, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dthera Sciences

Date: August 23, 2018

By: /s/ Edward Cox
Name: Edward Cox
Title: Chief Executive Officer

Exhibit 99.1

Dthera
SCIENCES

DTHERA SCIENCES RECEIVES FDA BREAKTHROUGH DEVICE DESIGNATION FOR ITS ALZHEIMER'S FOCUSED DEVELOPMENT-STAGE PRODUCT "DTHR-ALZ"

SAN DIEGO, CA. August 23, 2018 - Dthera™ Sciences (OTCQB:DTHR), the leading digital therapeutic company focusing on the elderly and individuals with neurodegenerative diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation to the Company's development-stage product, DTHR-ALZ.

DTHR-ALZ, if granted approval, would become the first non-pharmacological prescription treatment for the symptoms of Alzheimer's disease. The proposed indication for use states that "DTHR-ALZ is intended to mitigate the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type." To the Company's knowledge, Dthera Sciences is only the second digital therapeutics company to obtain Breakthrough Device designation from the FDA.

"Alzheimer's disease is a significant and rapidly growing public health crisis, and, among the 10 leading causes of death in the U.S., it is the only one that cannot be prevented, cured or slowed," said Edward Cox, CEO of Dthera Sciences, a publicly traded company based in San Diego. "We commend the FDA for recognizing this significant unmet medical need as well as the critical importance of providing innovative new treatments to patients with Alzheimer's and their caregivers. While we feel this ground-breaking recognition validates Dthera's mission to positively impact the lives of those effected by the disease, it also represents a meaningful advance for the entire digital therapeutic sector."

Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with medical device developers to expedite regulatory review in order to give patients more timely access to diagnostic and therapeutic technologies. According to the FDA, a "Breakthrough Device" is a product that may be more effective at treating or diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care. DTHR-ALZ is intended to be a prescription digital therapeutic that will deliver Reminiscence Therapy to patients with Alzheimer's disease. The device will use artificial intelligence to automatically optimize the therapy based on various forms of biofeedback from the patient. According to the Alzheimer's Association, Reminiscence Therapy is an evidence-based psychosocial intervention that has been shown in clinical trials to improve symptoms of the disorder, but the therapy's adoption has been limited because of the investment of caregiver time and resources. DTHR-ALZ, however, will seek to provide Reminiscence Therapy with more frequency, consistency and personalization while requiring minimal investment of time and resources.

Alzheimer's disease affects about 5.7 million people in the U.S. today, according to the Alzheimer's Association. With the aging population and few therapeutic options on the horizon, the impact of Alzheimer's disease is only expected to grow. The cost of care for dementia patients is predicted to increase from $277 billion in 2018 to more than $1.1 trillion by 2050.

"This Breakthrough designation has provided us with a remarkable opportunity to expedite the development of our digital therapeutic device," said Martin Culjat, Ph.D., VP of Scientific and Regulatory Affairs at Dthera Sciences. "We feel deeply honored that the FDA has confirmed DTHR-ALZ meets the requirements for this designation, and we are eager to work together with the FDA throughout this process."

DTHR-ALZ is not yet available for commercial use in the U.S.

About Dthera Sciences:

Dthera Sciences (OTCQB:DTHR) is the leading digital therapeutic company focusing on the elderly and individuals with neurodegenerative diseases. The San Diego-based, publicly traded company has two core products: ReminX™, a commercially available consumer health product for individuals suffering from social isolation and dementia; and DTHR-ALZ, a development-stage product that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with Alzheimer's disease.

Forward Looking Statements:

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Dthera's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our need for additional financing; uncertainties of intellectual property and patent protection; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any digital therapeutic technology under development, there are significant risks in the development, regulatory approval and commercialization of new products. Dthera expressly disclaims any obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (the "SEC"), and future periodic reports filed with the SEC on or after the date hereof. All of Dthera's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

Contacts:

Company Contact
Geno Kostikov, Corporate Development
Dthera Sciences
geno@dthera.com
(858) 215-5597

Media Relations
Joice Truban Curry, Publicist
c3 Communications, Inc.
joice@c3publicrelations.com
(858) 794-6974

Investor Relations
Marek Ciszewski, J.D., Managing Director, Head of Life Sciences
Liolios
DTHR@Liolios.com
(949) 574-38600