

# FDA Designates Breakthrough Device Status for MYnd Analytics' PEER 4.0

# A predictive data base and algorithm for reducing trial and error prescribing in mental health

MISSION VIEJO, Calif., Sept. 17, 2018 (GLOBE NEWSWIRE) -- MYnd Analytics, Inc. (NASDAQ: MYND), a market leader in improving the delivery of mental health through the combination of telemedicine and data analytics with augmented intelligence, today announced that the U.S. Food & Drug Administration (FDA) has granted Breakthrough Device designation for the Company's next generation product PEER 4.0.

PEER (the Psychiatric EEG Evaluation Registry) is the company's proprietary clinical phenotype database comprising over 40,000 medication outcomes for over 11,000 unique patients, which is used to predict how a patient will respond to a specific medication. The Company's original product, now in its third generation, has been continuously registered as a class 1 MDDS since October 2011.

Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with medical device developers to expedite regulatory review for diagnostic and therapeutic technologies that address a critical unmet need or a serious condition, where preliminary clinical evidence indicates substantial improvement compared to the current standard of care.

George Carpenter, CEO of MYnd stated, "This breakthrough designation highlights the growing evidence from the Company, National Institute of Mental Health (NIMH) and independent researchers of the predictive capacity of EEG data when paired with our unique, proprietary PEER Registry. We appreciate the FDA's determination that PEER meets the requirements for this designation and are eager to work together with the FDA going forward."

## **About MYnd Analytics**

MYnd Analytics, Inc. (www.myndanalytics.com) is a predictive analytics company that has developed a decision support tool to help physicians reduce trial and error treatment in mental health and provide more personalized care to patients. The Company's Psychiatric EEG Evaluation Registry, or PEER Online, is a registry and reporting platform that allows medical professionals to exchange treatment outcome data for patients referenced to objective neurophysiology data obtained through a standard electroencephalogram (EEG). Based on the Company's original physician-developed database, there are now more than 40,000 outcomes for over 11,000 unique patients in the PEER registry. The

goal of PEER Online is to provide objective, personalized data to assist physicians in the selection of appropriate medications. To read more about the benefits of this patented technology for patients, physicians and payers, please visit: <a href="https://www.myndanalytics.com">www.myndanalytics.com</a>.

MYnd also operates its wholly owned subsidiarity Arcadian Telepsychiatry Services, LLC which manages a suite of services including telepsychiatry, teletherapy, digital patient screening, curbside consultation, on-demand services, and scheduled encounters for all age groups. Arcadian utilizes patient engagement and re-engagement strategies so that care is effectively completed, helping to comfortably move inpatient care to outpatient, assisting patients in readjusting to their life routine, as well as reducing wait times for mental health treatment. Arcadian's customer base includes major health plans, health systems, and community-based organizations.

### **Forward-looking Statements**

Except for the historical information contained herein, the matters discussed are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements involve risks and uncertainties, such as statements regarding market developments, new products and growth strategies, the ability of MYnd's products to successfully produce objective data and improve efficiency in the treatment of depression and other mental health and psychiatric illnesses, as well as those risks and uncertainties set forth in MYnd's filings with the Securities and Exchange Commission. These risks and uncertainties could cause actual results to differ materially from any forward-looking statements made herein.

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Source: MYnd Analytics, Inc.