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Altoida's Vision For Alzheimer's Care Combines Digital Screening, Blood-Based Tests, New Drugs

by Marion Webb

Altoida CEO Marc Jones spoke with *Medtech Insight* about the company's investigational digital screening tool for Alzheimer's and the dire need for better, more accessible precision neurology diagnostics as the global population ages, neurologist shortages worsen, and groundbreaking Alzheimer's drugs change the treatment paradigm.

Medtech Insight sat down with Altoida's CEO Marc Jones at the recent LSX World Congress USA in Boston to learn more about the company's augmented reality- and machine learning-enabled system for assessing neurodegenerative disease.

The US Food and Drug Administration granted Breakthrough Device status to Altoida's tablet-based digital biomarker platform in 2021 for use as an adjunct to other diagnostic evaluations to predict disease conversion from mild cognitive impairment to Alzheimer's disease within 12 months.

Jones discussed the dire need for better screening tools as new Alzheimer's drugs are expanding options for treating and preventing the disease. With a rising aging population and shortage of neurologists, primary care doctors will need to rely on better screening tools to identify patients with mild cognitive impairment or more advanced disease so they can receive the right treatment at the right time to delay disease onset or slow down progression.

This interview has been edited lightly for clarity and length.

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Source: Altoida

Medtech Insight: What are the major challenges in diagnosing and treating Alzheimer's disease today?

Marc Jones: Obviously, this is a very large global problem. Alzheimer's specifically, but neurodegeneration broadly, there's recent research that said that over 2,000 people per day are moving to more advanced stages of disease. The problem is that we have a shortage of dementia specialists, an aging population, and we now have drugs, so people want access to drugs, but the problem is that clinicians [especially primary care doctors who see patients first] lack the right tool sets. The diagnostic journey today is that you go to the primary care physician and say that 'dad has been forgetful lately,' after which the doctor advises to 'keep an eye on it' and to come back in two to three months. Then you come back and the primary care doctor refers you to a neurologist, which will take another six to nine months because of the high demand for neurologists. There are two bad things happening here: the long wait to see a neurologist, and you're sending an unqualified issue to a neurologist. You don't know if the person is truly impaired. The specialist has to run a full neuropsych evaluation, which can take three to four weeks for the paper-based evaluation, and then the patient may need an MRI or amyloid-PET scan, which can take another six weeks to complete. At the 2024 Alzheimer's Association International Conference, Soeren Mattke, director of the

Empowering Primary Care Physicians With Digital Biomarkers For Early Alzheimer's Detection

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Altoida CEO Mark Jones has high hopes that the company's digital assessment tool will be approved by the FDA to be used along with blood biomarker testing by primary care doctors to help predict Alzheimer's disease before patients show symptoms.

Read the full article here

University of Southern California Brain Health Observatory, warned that if current diagnostics methods remain unchanged, the delay in Alzheimer's diagnosis could extend to 70 months by 2033.

Q How does Altoida's cognitive assessment compare with current cognitive tests performed in the primary care setting?

A Jones: The baseline test that many primary care physicians use tends to overindex on memory and isn't as sensitive to things like functional decline, and functional decline is what really matters. There's a whole slew of tests, but they were designed for later-stage deficits. We were part of an independent research study called RADAR-AD, a European research project focused on developing digital tools for remote monitoring of Alzheimer's disease progression, which showed that Altoida was able to pick up preclinical Alzheimer's disease, something RADAR-AD said is not possible by current methods. That's really important, because if you look at the Eisai and Eli Lilly data [both companies brought new, game-changing drugs to market after a long spell with no major innovations], their performance of the drug was better with people in earlier stages. So identifying as early as possible is really going to be the holy grail for dementia diagnostics.

Q How about blood tests that have shown promising in the early detection of Alzheimer's disease, how do you see Altoida's solution fitting into the early detection paradigm for Alzheimer's disease?

A Jones: The two Alzheimer's drugs that are available today [aim to] remove amyloid plaques from the brain. There is the p-tau 217 blood test, which studies have shown looks promising, but here's an important point. Pathology is necessary, but not sufficient. I believe that our test, combined with ultimately a blood biomarker, will be sufficient to at least significantly accelerate the diagnostic journey, if not allow primary care physicians at some point to diagnose mild cognitive impairment and move people to treatment. Because again, if you look at the label for *Eisai (Liaoning) Pharmaceutical Co. Ltd.* and*Biogen, Inc.*s drug Leqembi [lecanemab] or *Eli Lilly and Company*'s Kinsula [donanameb-azbt], you need to have a functional cognitive test

and a test showing pathology. And that would allow both those things to happen in the primary care office, which today is not possible. Also, both FDA and CMS [Centers for Medicare & Medicaid Services] have told the drug developers that they want to see quality of life improvement – how do you prove that your drug is improving one's quality of life? That's really challenging. Quality of life is the ultimate measure. Because we're simulating the activities of daily living with our augmented reality, we can now establish a baseline with a patient, and then once they are on the drug, we can see how they are progressing from that baseline to see if they are improving. FDA said when they improved Leqembi it's not enough to show they remove the amyloid plaque; we need to see quality improvement. So Eisai and Lilly need to do registry studies and show that over time these drugs are making a meaningful impact on patients.

Q **Altoida's platform technology has been used as part of later-stage clinical trials by pharmaceutical companies developing Alzheimer's drugs. What was Altoida's role exactly and what did you learn from those studies?**

A Jones: We've supported pharma as an investigational-use product, helping to enrich populations to go into trials and also monitoring treatment response for patients that are clinical trials. We have applied our technology in multiple global studies over hundreds of sites in more than a dozen countries and continue to do that. We are seeking to provide the tools they need so they can remove those bottlenecks. There are some 6,000 to 8,000 neurologists, but there are hundreds of thousands of primary care clinicians. In San Diego, you can get a PET scan relatively straightforward, but if you are in middle America, maybe that's a two- or three-hour drive to get a PET scan. The advent of blood markers, and a platform like Altoida's – that's health care accessibility. We are trying to drive clinical performance so we can provide real diagnostics to people that need it so they can get on the drugs that they need. [In 2021, Altoida announced it secured funding and research partnership with Eisai Innovation to accelerate work toward predictive dementia diagnostics. Jones confirmed that the two companies are conducting a multi-year observational study in Greece.]

Q **What will the role of PET scans be in the future?**

A Jones: My hope is that it eliminates the need for PET. What I'm rooting for is that these blood biomarker developers show such correlation to PET that you no longer need PET. Every time I go to my primary care doctor for my annual physical, they draw blood. PET scans are expensive.

Q **How is the Altoida platform currently being accessed and what are your plans for the future?**

A Jones: Right now we're using iPads. Down the road we expect to use non-IOS-based devices as well. The patient is self-administering the test in the clinic with a clinician in the room observing them. Eventually, I would love to be in a spot where patients have a remote indication as well. It would be great to be able to allow these people to download the app and do this at high frequency at home. There are certain things we have to confirm before we can get the remote indication, and that's something we're certainly looking at.