



AULT GLOBAL HOLDINGS

Ault Global Holdings Announces That Alzamend Neuro Has Submitted an IND Application for AL001 for Dementia Related to Alzheimer's Disease

July 1, 2021

LAS VEGAS--(BUSINESS WIRE)--Jul. 1, 2021-- [Ault Global Holdings, Inc.](#) (NYSE American: DPW) a diversified holding company (the "**Company**"), announced today that [Alzamend Neuro, Inc.](#) (Nasdaq: ALZN) ("**Alzamend**"), a preclinical stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, submitted an investigational new drug ("**IND**") application to the FDA for the initiation of a Phase 1 clinical study of [AL001](#) on June 30, 2021. The Phase 1, first-in-human study, is designed for the purpose of determining potential clinically safe and appropriate AL001 dosing in future studies. AL001 is a lithium-based ionic cocrystal oral therapy for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's disease.

Following completion of this initial study, Alzamend intends to initiate a Phase 1/2a clinical trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of AL001 in Alzheimer's disease patients. Presuming favorable data, a subsequent Phase 2b program is planned to target appropriate doses for the pivotal Phase 3 safety/efficacy clinical program required for regulatory approval.

"This IND submission represents a key milestone for Alzamend as we continue to advance our proprietary pipeline. We believe AL001 could potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's disease and other neurodegenerative diseases and psychiatric disorders. We look forward to providing more details on the timeline and market opportunity following FDA clearance of the IND, if obtained," commented Stephan Jackman, Chief Executive Officer of Alzamend.

Based on preclinical data, AL001 treatment prevents cognitive deficits, depression, and irritability in APPSWE/PS1dE9 mice, and has shown an improvement of associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease and psychiatric disorders. Lithium has been marketed for more than 35 years and human toxicology regarding lithium use has been well characterized, potentially allowing Alzamend to rely upon this existing data, potentially reducing the regulatory burden for safety data.

Alzamend's mission is to help the Alzheimer's disease community by supporting the full product development life cycle of treatment and cures for dementia and Alzheimer's disease driven by the belief that strong support of research is the foundation for true innovation. Dementia is not a normal part of aging, and there are numerous symptoms that can indicate cognitive and neurological impairments. Alzheimer's disease is the most common form of dementia. This disease robs people of their loved ones, as memories are erased and personalities are diminished. Alzamend's vision statement nicely sums up their mission: "**Together We Can 'Make Alzheimer's Just a Memory!**'™".

The economic impact of Alzheimer's disease can be as devastating as the emotional stress. Over 47 million people in the world currently live with Alzheimer's disease or dementia, with over 6.2 million in the U.S. (two-thirds are women). The lifetime cost of care for an Alzheimer's disease patient is estimated at \$374,000 in the U.S. According to the Alzheimer's Association, it is estimated that Alzheimer's and dementia deaths increased more than 16% in 2021 due to COVID-19. In 2021, Alzheimer's and dementia will cost the U.S. an estimated \$355 billion with the costs expected to rise into the trillions in the next 25 years. In addition, Medicare and Medicaid is expected to pay approximately \$239 billion, or 67% of the treatment and long-term care costs associated with Alzheimer's disease and dementia, with another \$79 billion of out-of-pocket costs. According to the Alzheimer's Association, eleven million Americans provide an estimated 15.3 billion hours of unpaid care per year, valued at \$257 billion, for these patients with two-thirds of these being women, and one-third being daughters.

Milton "Todd" Ault, III, the Company's Executive Chairman, stated, "The Company is pleased that Alzamend has achieved this milestone to further its commitment to develop treatments and cures for Alzheimer's, other neurodegenerative diseases and psychiatric disorders."

The Company has certain beneficial ownership and rights to further invest in Alzamend as follows:

- The Company beneficially owns approximately 5.3 million shares of Alzamend common stock held by its wholly owned subsidiary, [Digital Power Lending, LLC](#) ("**DPL**").
- The Company has the right to acquire 1.35 million shares of Alzamend common stock upon the exercise of warrants beneficially owned by DPL.
- In March 2021, Alzamend entered into a securities purchase agreement with DPL pursuant to which Alzamend agreed to sell an aggregate of 6.7 million shares of its common stock for an aggregate of \$10 million, or \$1.50 per share, which sales will be made in tranches. Alzamend further agreed to issue to DPL warrants to purchase such number of shares of its common stock equal to 50% of the shares of common stock purchased under the securities purchase agreement at an exercise price of \$3.00 per share. On March 9, 2021, the Company purchased 2.7 million shares of Alzamend common stock (included in the 5.3 million shares of Alzamend common stock held by DPL described above) upon closing of the first tranche of \$4 million. Under the terms of the securities purchase agreement, DPL may purchase an additional 4.0 million shares.
- Finally, Alzamend agreed that for a period of 18 months following the date of the payment of the final tranche of \$4 million,

DPL will have the right to invest an additional \$10 million on the same terms, except that no specific milestones have been determined with respect to the additional \$10 million.

Should the Company exercise all warrants and options to invest, it would own approximately 22.6 million shares with an average cost of \$2.27 per share of common stock, representing 22% of Alzamend's issued and outstanding common stock.

For more information on Ault Global Holdings and its subsidiaries, the Company recommends that stockholders, investors and any other interested parties read the Company's public filings with the SEC, available at www.sec.gov, and press releases available under the Investor Relations section at www.AultGlobal.com.

About Ault Global Holdings, Inc.

Ault Global Holdings, Inc. is a diversified holding company pursuing growth by acquiring undervalued businesses and disruptive technologies with a global impact. Through its wholly and majority-owned subsidiaries and strategic investments, the Company provides mission-critical products that support a diverse range of industries, including defense/aerospace, industrial, automotive, telecommunications, medical/biopharma, and textiles. In addition, the Company extends credit to select entrepreneurial businesses through a licensed lending subsidiary. Ault Global Holdings' headquarters are located at 11411 Southern Highlands Parkway, Suite 240, Las Vegas, NV 89141; www.AultGlobal.com.

About Alzamend Neuro

Alzamend Neuro, Inc. ("Alzamend") (www.Alzamend.com), is a Delaware corporation with its corporate headquarters in Tampa, Florida. The mission of Alzamend is to help the Alzheimer's community by supporting the full product development life cycle of treatment and cures of neurodegenerative diseases and psychiatric disorders, including Alzheimer's disease. With Alzamend's two current and future product candidates, Alzamend aims to bring treatments or cures to market at a reasonable cost as quickly as possible. Alzamend's current pipeline consists of two novel therapeutic drug candidates, AL001 - a patented ionic cocrystal technology delivering a therapeutic combination of lithium, proline, and salicylate, and AL002 - a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient's immunological system to combat Alzheimer's disease. Both of Alzamend's product candidates are licensed from the pursuant to royalty-bearing exclusive worldwide licenses from the University of South Florida. www.Alzamend.com

Forward-Looking Statements

This press release contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "believes," "plans," "anticipates," "projects," "estimates," "expects," "intends," "strategy," "future," "opportunity," "may," "will," "should," "could," "potential," or similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties. Forward-looking statements speak only as of the date they are made, and the Company undertakes no obligation to update any of them publicly in light of new information or future events. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors. More information, including potential risk factors, that could affect the Company's business and financial results are included in the Company's filings with the U.S. Securities and Exchange Commission, including, but not limited to, the Company's Forms 10-K, 10-Q and 8-K. All filings are available at www.sec.gov and on the Company's website at www.AultGlobal.com.

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